REDACTED DOCUMENTS RELATING TO DOCKET 7315

EXHIBIT A – Previously filed redacted in DKT 8118

EXHIBIT B – No redactions

EXHIBIT C – No redactions

EXHIBIT D – Previously filed redacted in DKT 8118

EXHIBIT E – Previously filed redacted in DKT 8118

EXHIBIT B

VERITEXT
LEGAL SOLUTIONS

Deposition of:

Robert McMeeking , Ph.D.

July 6, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS	CASE NO.
PRODUCTS LIABILITY LITIGATION	MD-15-02641-PHX-DGC

VIDEOTAPED DEPOSITION OF ROBERT M. McMEEKING, Ph.D.

THURSDAY, JULY 6, 2017

REPORTED BY: MONICA T. CORLEY, CSR NO. 8803

VIDEOTAPED DEPOSITION OF ROBERT M. McMEEKING, Ph.D., THE WITNESS, TAKEN ON BEHALF OF THE DEFENDANTS, AT 9:06 A.M., THURSDAY, JULY 6, 2017, AT 401 STORKE ROAD, GOLETA, CALIFORNIA, BEFORE MONICA T. CORLEY, CMR, CRR, CSR NO. 8803.

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GEOFF MINGER, VIDEOGRAPHER

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EXHIBITS

EXHIBITS (CONTINUED)

EXHIBITS (CONTINUED)

EXHIBITS (CONTINUED)

NO.	PAGE	DESCRIPTION
EXHIBIT 18	208	ARTICLE ENTITLED "LONG-TERM RESULTS OF THE SIMON NITINOL INFERIOR VENA CAVA FILTER," BY POLETTI, ET AL.

GOLETA, CALIFORNIA;
THURSDAY, JULY 6, 2017, 9:06 A.M.

(Whereupon, Deposition Exhibits 1 through 11 were pre-marked for identification by the Court Reporter.)

THE VIDEOGRAPHER: Good morning. We are on the record at 9:06 a.m. on July 6, 2017. This is the video recorded deposition of Robert McMeeking, Ph.D.

My name is Geoff Minger, here with our court reporter Monica Corley. We are here from Veritext Legal Solutions.

This deposition is being held at 401 Storke Road in Goleta, California. The caption of the case is In Re: Bard IVC Filters Liability Litigation filed in the United States District Court for the District of Arizona, Case No. MD-15-02641-PHX-DGC.

Would Counsel please identify themselves for the record, and state their appearances.

MR. O'CONNOR: Yes. My name is Mark O'Connor, and I represent the plaintiffs.

MS. DALY: I'm Taylor Daly for the Bard defendants.

THE VIDEOGRAPHER: Those present on the phone.

MS. DALY: They don't make appearances.

MR. O'CONNOR: They don't need to make appearances.

THE VIDEOGRAPHER: Okay. The witness will be sworn in, and Counsel may begin the examination.

ROBERT M. McMEEKING, Ph.D.,
having been first duly sworn, was
examined and testified as follows:

EXAMINATION

BY MS. DALY:

Q Dr. McMeeking, we've met several times before.

A Yes, we have.

Q How are you today?

A Very well, thank you.

Q Good.

I went ahead and premarked a couple of things before we started the deposition, so let's just go through those.

The first item is marked Exhibit 1, and

that is a new updated curriculum vitae that you handed me this morning, correct?

A That's correct.

Q Can you tell me what areas include something new?

A There's three areas. There's a few papers that I've added to the list of publications. I have a new title at UCSB, although that may be on the last curriculum vitae that I submitted, because in addition to being emeritus professor of structural materials, I'm distinguished professor of mechanical engineering and distinguished professor of materials. And then the third area where there is an addition is that I have been elected the president of the International Congress on Fracture, which actually happened last month, so I'm the president of that organization for four years.

Q On your three new papers, what do they talk about?

A It may not be three new papers but -- I didn't count how many new papers there are, but there's a number of new papers, and they outline -- I need to refer to the list to --

Q Sure.

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A -- give you that information.
There is one on adhesion, there's one on plasticity in high temperature nickel-based alloys, there's one on the behavior of materials called hydrogels, there's one on calculations for lithium ion batteries, and there's a number of other similar papers but they're all along those lines in terms of the areas which are involved.
Q Are any of them relating to nitinol materials?
A No.
Q Or to IVC filters?
A No.
Q Okay. Thank you.
All right. Then I marked as Exhibit 2 what I call your main report in the MDL litigation that's dated 3-17 of 2017, correct?
A I need to look at the date, which is in the middle of the report. Page -- March the 3rd, 2017.
Q Oh, sorry. Okay.
A Yeah.
Q March the 3rd. All right.
And then what I've marked as Exhibit 3 is the Supplementary Report specific to Meridian and

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Denali that's dated at the top April 7, 2017, correct?
A Correct.
Q And then I marked as Exhibit 4 a report by you called Rebuttal Report dated May 11, 2017?
A Correct.
Q All right. Now, let me go ahead and show you what I've marked 5, 5A and 6. 5 and 5A are copies of bills that you gave me, where the bills are dated November 6, 2016; and Exhibit 6 is a bill dated April 18, 2017.
Starting with 5 and 5A, would you just tell me basically what work was that that was being done and through what time frame?
A The work on that was in regard to the case Austin versus Bard and it was expert witness work for the plaintiff, and the time involved ranges from the 8th of April 2016 to the 31st of August 2016.
Q All right. And then 5A, what is that?
A 5A is the bill I submitted for a deposition that took place on 19th of July 2016 in connection with the Austin versus Bard case.
Q All right. And then let's look at 6, and tell me what the work is on -- that's represented

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on that invoice and through what period of time.
A The work represented in this invoice is in connection with the Bard MDL cases and is for expert witness work for the plaintiff, or the plaintiffs, and the dates involved range from 18th of January 2017 to the 2nd of April 2017.
Q Okay. Now, is there work that you have done since the time of that invoice?
A Yes.
Q And what period of time and approximately how much have you billed?
A Well, from the 3rd of April 2017 -- I have not billed that, that time.
Q Okay.
A But the dates are from the 3rd of April 2017 to yesterday, and the number of hours involved is approximately 110.
Q What did you do for preparation for your deposition today?
A I reviewed a number of documents, including the reports that you have marked as exhibits, and then I read a number of papers that are connected to the case, these are scientific papers that are connected to the case, and I read expert reports of individuals appearing for the

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defense and individuals appearing for the plaintiffs.
Q Which individuals for the Bard did you read in preparation for today?
A I read the reports by Dr. Fasching. I read the reports by Dr. Briant.
Q Anybody else?
A Well, in the past I've read reports by medical experts who provided reports in connection with case-specific individuals, but I did not review them in the last few -- last week or so --
Q Okay.
A -- for the deposition.
Q Now, I'm going to show you, just while we're talking about exhibits that we're getting on the record, I've marked as 7, 8, 9, 10 and 11 five case-specific reports that you did in the Bellwether cases. So 7 is on Ms. Booker's case. If you just confirm "yes" when I hand these to you.
A Yes, that's correct.
Q 8 is in Mrs. Hyde's case?
A Yes, that's correct.
Q 9 is Doris Jones?
A Yes, that's correct.
Q 10 is Carol Kruse?

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A Yes, that's correct.
Q And 11 is Debra Mulkey?
A Yes, that's correct.
Q Did you read any case-specific reports of any expert for Bard or the plaintiffs in connection with your work in writing those case-specific reports or in preparation for today's deposition?
A Yes. In -- in preparation for writing the case-specific reports, I consulted reports by Dr. Darren Hurst, Dr. Derrick Muehrcke, and Dr. Robert Richie.
Q So Hurst, Muehrcke and Richie?
A Correct. Yes.
Q For the case specific?
A Yes.
Q Okay. Did you see any Bard medical case-specific reports?
A On those individuals?
Q On those individuals.
A No.
MR. O'CONNOR: Object to the form.
BY MS. DALY
Q Okay. What reports have you read of plaintiffs' experts in preparation for today?
A I read reports by Dr. Richie. I read

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reports by Dr. Parisian and by Dr. Kessler. And I should say that I also read, in preparation for the case, some transcripts of depositions, which I didn't mention before.
Q And who did you read transcript-wise?
A I read transcripts of depositions of Dr. Fasching. I read an old -- not old, a deposition in the Austin case by Dr. Briant. I read deposition by Dr. Richie. And I believe that's it.
Q Okay. All right. I'm going to start with Exhibit 2, which is your main report.
All right. So Exhibit -- Exhibit 2, your March 2017 MDL report, on page 5, that references the IMDRF/GHTF standards?
A Correct.
Q In your Section 3.2.1, right?
A Yes, that's right.
Q All right. What is the IMDRF/GHTF?
A It's an international organization that coordinates regulatory -- not so much coordinating regulatory affairs but coordinates the activities of regulators and industrial participants and academics in terms of processes, procedures and concepts that are relevant to the regulation of

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medical implant devices.
Q Does it direct or regulate the FDL?
A The FDA?
Q The FDA.
A No. No.
Q It does not establish their regulations?
A It does not establish their regulations.
Q Does it oversee them in any way?
A Not to my knowledge.
Q Okay. And to what industries does it apply? You said medical devices?
A Medical implant devices.
Q So it has to be medical and implantable?
A I believe so.
MR. O'CONNOR: Form. Foundation.
THE WITNESS: It may cast a wider remit, but I don't know whether other devices and systems are involved.
BY MS. DALY:
Q Okay. Has the United States FDA formally adopted the standards for application to devices that fall under the FDA's jurisdiction?
MR. O'CONNOR: Form and foundation.
THE WITNESS: Not to my knowledge.
BY MS. DALY:

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Q Has the FDA formally issued any comments on the applicability of those standards to medical devices it has jurisdiction over?
MR. O'CONNOR: Form and foundation.
THE WITNESS: Not to my knowledge.
BY MS. DALY:
Q Has the FDA ever stated that medical devices presented to it via 510(k) submissions must follow the standards of IMDRF/GHTF?
MR. O'CONNOR: Form and foundation.
THE WITNESS: Not to my knowledge.
BY MS. DALY:
Q Section 3.2.1 in paragraph 1 of your report states "Medical devices should be designed and manufactured so they will perform as intended by the manufacturer and not compromise the clinical condition or safety of patients."
Did I read that right?
A Well, it says "for the purposes intended and where applicable." I don't see where it says "by the manufacturer." But other than that, I agree with your reading of the sentence.
Q Okay. And you agree with me that's a very general statement about product development and manufacture?

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A Well, yes.
MR. O'CONNOR: Form.
THE WITNESS: And it -- it would apply to more than just medical implant devices.
BY MS. DALY:
Q And what I just read, is that a direct quote from the standards or is that a summarization of yours?
A Well, as far as I remember, it's a direct quote. But let me read.
Q I only ask that because it doesn't have quotes around it. That's --
A Oh, yeah, it's -- it is, to my recollection, a direct quote from the principles, which are enunciated by what is now GHTF.
Q You did not cite to an exact portion of those standards in this paragraph 1.
A I --
Q In other words, I don't have a page, I don't have a section from the GHTF --
A May I look?
Q -- that I could go to. Do you know if you did that?
A Well, I looked at a specific page to obtain those paragraphs.

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Q Okay.
A So it references 9 --
Q Uh-huh.
A -- in the list of references, and there's information there which I believe will enable me to find the page which is involved. Namely, the GHTF/SGI/N68:2012, 2nd November 2012 information.
Q Okay. And I was just asking, did you cite anything more specific, like it's page 10, section such-and-such? You just -- you just cited to the standards generally?
A Yes.
Q Okay. Paragraph 2, moving on in your report, states that "When risk reduction is required," do you see that sentence -- that --
A Starting --
Q -- the third line?
A Starting on the third line?
Q Uh-huh.
A Yes. Yes.
Q What does that mean, "When risk reduction is required"?
A Well, when the manufacturer or the engineer is trying to reduce the risks that a device presents to anyone who receives the device,

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then that is the process of risk reduction.
Q And there are -- in your experience, are there situations when after design and manufacture and a product goes to market, the manufacturer recognizes that there are some risks they might not have understood in the development process?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: Yes, that can happen.
BY MS. DALY:
Q And that when risk reduction is required might indicate that a manufacturer should look at that situation?
A I would agree with that statement.
MR. O'CONNOR: Object to the form of the question.
BY MS. DALY:
Q All right. Paragraph 2 goes on to say at the fifth line there that "A manufacturer should identify" -- first of all, are you with me?
A Yes. Yes.
Q All right. "Should identify known or foreseeable hazards and estimate the associated risks arising from the intended use," I'm skipping forward a little bit, "eliminate risks as far as

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reasonably practical through inherently safe design and manufacture, reduce as far as reasonably practicable the remaining risk by taking adequate protection measures, including alarms and inform users of any residual risks."
Is that what the standard says?
A Yes, that's what it -- yeah, that's what the standard says. The principle. The principle.
Q So let's take that last comment first, if I could. Is it your opinion that Bard did not inform users of risks in its products?
A They informed users of risks in their products. What I'm not aware of is whether they fully informed the users of the risks.
MR. O'CONNOR: Belated objection to form and foundation.
BY MS. DALY:
Q So you know that, for example, Bard submitted with its products Information For Use documents, correct?
A Yes.
MR. O'CONNOR: Form and foundation.
BY MS. DALY:
Q And that from time to time it issued "dear doctor" or "dear colleague" letters?

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A That is my understanding.
Q And do you also understand that the FDA reviewed and approved those IF Use and dear doctor letters?
MR. O'CONNOR: Form. Foundation.
THE WITNESS: I don't know of that for a fact in this particular case, but I -- I assume that that is the process which is involved.
BY MS. DALY:
Q And then backing up to the prior statement in that paragraph, that "The manufacturer should reduce as far as reasonably practicable the remaining risks by taking adequate protection measures," what risks associated with Bard filters do you think Bard needed to reduce as reasonably practicable?
A I think they should have tried to reduce the risks of tilting, perforation, migration and fracture by fatigue.
Q Are those risks that you've just identified risks that are known to be associated with all IVC filters?
MR. O'CONNOR: Form and foundation.
THE WITNESS: As far as I know, there are such risks in many of the filters which are on the

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market.
BY MS. DALY:
Q Is it your opinion that Bard failed to reduce as far as reasonably practicable the remaining risks by taking adequate protection measures?
A Can you repeat the question, please.
Q Yes.
Is it your opinion that Bard failed to reduce as far as reasonably practicable the remaining risks by taking adequate protection measures?
MR. O'CONNOR: Form and foundation.
THE WITNESS: In certain of the designs of the filters those risks, in my opinion, were not reduced to the extent practicable, and I would say that that applies to all of the models that we are discussing in the -- in the present case.
BY MS. DALY:
Q And which risks do you identify -- that you have an opinion that Bard failed to reduce?
A The risks of tilting, perforation, migration and fracture by fatigue.
Q Have you determined by any research or any other method that any other manufacturer of

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percutaneously retrievable IVC filters have been able to reduce as far as reasonably practical -- practicable by taking adequate protection measures any of those risks you just identified?
MR. O'CONNOR: Form and foundation.
BY MS. DALY:
Q In filters.
A I have not investigated that in many cases, and in other cases I'm under restrictions in terms of what I can say when I have been involved in investigating that.
Q Do you rely on any of the work that you have done that you cannot talk to me about for your opinions in this case?
A No.
MR. O'CONNOR: Form.
BY MS. DALY:
Q So anything that you have learned either as a consulting expert or a retained expert with respect to other IVC filters you do not rely on for your opinions in the Bard litigation?
A Yeah, I do not rely on that other information.
Q Okay. And I'm aware that you've been retained in the Cook litigation.

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A That's correct, yes.
Q Because that's been public. Okay.
I think you just said a moment ago that with respect to all of Bard's retrievable filters, that is from the Recovery to the Denali, that it is your opinion that Bard has not done what is reasonably practicable to take adequate protection measures against tilt, perforation, migration and fracture?
A That's correct.
Q Okay. Is it your opinion that the various modifications that Bard has made along the way to its retrievable IVC filters did nothing to reduce the risks associated with either tilt, perforation, migration or fracture?
MR. O'CONNOR: Form.
THE WITNESS: The -- some of the changes that were made would have some effects on one or more of those phenomena that can take place in filters, and in some cases it's unclear whether the measure taken had the effect intended, but -- but there would have been some benefits from some of the changes which were made.
BY MS. DALY:
Q Have you specifically modeled any filter

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from the G2X, Eclipse, Meridian or Denali models?
A I've modeled the G2X. I have modeled all of the filters in the sense that I've made the assessment that they all have similar characteristics and, therefore, in certain of the aspects of the behavior, the response will be the same -- will be very similar in each of the filters.
Q When you say "model," with respect to the G2X on to the Denali, you've looked at design drawings, correct?
A Correct.
Q And you've taken -- you've looked at the measurements of the, you know, length of legs or width of legs, those sorts of things, correct?
A Well, I've relied on the engineering drawing to give me the values of those lengths.
Q So in that sense you've -- you've modeled from the design drawings, correct?
A Well, I should -- I should clarify my response.
I have looked at those drawings and I've compared all the filters with each other in terms of their size and shape and so on, and then that has allowed me to make a deduction that my modeling

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of the G2 and the G2X is representative of the behavior that one would expect to see in the models namely the Eclipse, the Meridian and the Denali. Although not exactly the same, there would be similar behavior in each of these other three filters.
Q Have you done any FEAs specific to the Eclipse, the Meridian or the Denali?
A I have not done FEA analysis specific to the Eclipse, Meridian and Denali.
Q And you have not done work that would tell you what the specific modifications of filters that Bard has -- has included would do with respect to, for example, loads on the filter, strains that the filter is --
A I have not --
MR. O'CONNOR: Form and foundation.
BY MS. DALY:
Q Let me finish.
MR. O'CONNOR: Let her finish the question.
BY MS. DALY:
Q Let me finish.
-- strains that the filter sees or loads that are put on those filters?

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MR. O'CONNOR: Form and foundation.
THE WITNESS: I have not done any calculations that specifically identify the detailed differences that would occur because of the design changes going from the G2X through to the Denali.
BY MS. DALY:
Q So going back to the language of the standard, on what do you base your opinion that Bard has not done what is reasonably practicable to take appropriate protection measures in any of its retrievable filters against the complications that you identified?
A Well, part of the issue is that they should have taken certain measures sooner than they ultimately did and that the measures that they eventually took were not necessarily effective at reducing the risk to the extent practicable and they didn't investigate the consequences -- they didn't investigate thoroughly the consequences of the trade-offs that were involved in the design changes to modify the filters from the G2 through -- G2X through to the Denali.
Q How would they have done that differently?
A Well, they would have done more

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investigations of the behavior in bench tests and they would -- they should have designed bench tests that were more effective at investigating the behavior that you would expect to see in the filter when it was eventually implanted in the -- in patients. And they perhaps should have done animal tests as well, but I will not comment specifically on what those animal tests should have been.
Q And you haven't yourself done any further investigations beyond what Bard did to see if you can determine, through investigation, whether Bard in fact failed to understand or determine some characteristic in their filter that was leading to complications?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: I -- I have not done such investigations.
BY MS. DALY:
Q And you also have not developed any bench testing that you think would have been better testing that Bard could have done to reveal something about their filter that identified information about these complications?
A I don't do bench testing, so no, I haven't

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developed any bench tests.
Q And you just said you hadn't done any animal testing and you didn't --
A No.
Q -- have any ideas of protocols?
A I don't do animal testing and I --
Q Okay. With respect to the comment you just made about Bard should have taken certain measures sooner, we've talked about some of these before. The electropolishing issue, for example, you've testified before that you thought they should have done that earlier?
A I believe I said I rely on prof- -- Dr. Richie in regard to the question of electropolishing the wires that are in the filters.
Q Okay. So with respect to an opinion that Bard could have electropolished its retrievable filters before it did so in the Eclipse, you're not going to give that opinion, you defer to Dr. Richie?
A Well, I --
MR. O'CONNOR: Form and foundation.
THE WITNESS: I'll defer to his opinion in terms of the wires, but a point I would like to make is that they could have switched to using tube

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materials sooner, and they could have made the material out of tube material which they could -- which they could have electropolished at the stage of -- of making the filters from tube material rather than wires.
BY MS. DALY:
Q I'm sorry, I'm missing what that word is. What materials?
A Oh, so --
Q You said troop?
A Tube.
Q Tube materials.
A Tube, yeah.
Q Got it.
A T-u-b-e.
Q Okay. Do you know of any manufacturer that was using tube materials to make IVC filters before the time that Bard came out with the electropolished Eclipse?
A No.
Q Do you have any papers you can cite me to that that -- that one could electropolish wire adequately to have it improve any characteristic of an IVC filter before Bard did so in the Eclipse?
MR. O'CONNOR: Form.

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THE WITNESS: I've -- I've not investigated that aspect of the situation, and as I said before, I defer to Dr. Richie in regard to electropolishing wires.
BY MS. DALY:
Q Are there any other changes that you think Bard later made to its filters that it could have made earlier --
A Yes.
Q -- to -- to impact resistance to complications?
A Yes.
Q All right. And what are those?
A They could have developed caudal anchors sooner than they ultimately did. They could have developed penetration limiters sooner than they ultimately did. And they could have redesigned the filter configuration to try and find a better -- a better combination of -- of -- of phenomena that would improve the behavior of the filter in terms of the risks involved.
Q All right. So let's talk about caudal anchors and limiters. On what do you base your opinion that Bard could have added caudal anchors and limiters earlier than it did?

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A Well, the -- the reason is that they eventually did put caudal anchors on the filters, and so my point is simply that they could have started to consider that possibility sooner than they -- they did, once they realized that caudal migration was contributing to tilt and tilt was contributing to other failures that the filter was experiencing.
Q Okay. Do you know of any other IVC filter manufacturer who incorporated anchors or limiters earlier than Bard did?
MR. O'CONNOR: Form and foundation.
THE WITNESS: Not to my knowledge.
BY MS. DALY:
Q Okay. Do you know any -- do you know in any in-depth way what the process was internally in Bard to develop these anchors and limiters?
MR. O'CONNOR: Form.
THE WITNESS: I've read some of the documents that describe activities that were involved, but I -- I wouldn't say that I know in detail what the processes were that were involved in developing those caudal anchors.
BY MS. DALY:
Q Do you know -- do you know of design

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efforts that Bard made to add these anchors and limiters that were unsuccessful initially and more changes had to be made?
MR. O'CONNOR: Form.
THE WITNESS: I do know that some of the designs of the caudal anchors that they investigated did not work as well as others.
BY MS. DALY:
Q The other thing you talked about was that Bard could have redesigned the configuration of its filters. It was a little vague to me. What do you mean by that?
A Well, I mean the -- the shape of the limbs, the dimension of the limbs, in other words their -- their diameter, they could have considered different numbers of limbs, they could even have considered moving to a different material. So there's a fairly large number of design choices that could have been considered, and they could well have come up with a combination of features in the design that gave them a better combination of -- of phenomena in terms of how the filter behaved.
Q Do you know -- are you aware of any steps that Bard took along the way from Recovery to

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Denali to look specifically at shapes, diameters of limbs, numbers of limbs, new materials?
A Well, when they went from the Recovery to the G2, they changed the shapes and the lengths of -- of the limbs. When they went to the G2X, they made some changes to the details of the cap shape. And then of course the next big change -- adding caudal anchors and electropolishing were changes, but the next big change was moving to the Denali where they use a tube instead of wires to design the -- the filter. But I'm not aware of whether they considered other changes such as changing the number of limbs or moving to a different material.
Q Have you done any work to -- to look at combinations of things like type of material, diameter, shapes of limbs, numbers of limbs, that you think would cause an IVC filter to perform better?
A Well, in --
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: In this case, I've done a comparison of the -- of the Recovery through Denali line of filters with the Simon nitinol filter.

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BY MS. DALY:
Q Uh-huh.
A And in other activities, which I cannot talk about, I've made similar comparisons among filters.
Q But you've said you're not going to rely in this case on the comparisons you made in the cases you can't talk about, right?
A That's correct.
Q All right. So we'll set that aside for a moment. But you -- you have developed no prototype making changes to any of Bard's filters that you think would perform better, correct?
MR. O'CONNOR: Form.
THE WITNESS: No, I've -- I've developed no prototype to attempt to -- to achieve that objective.
BY MS. DALY:
Q And of course since you don't have a prototype for that, you've not bench tested such a prototype to see how it would perform either, true?
A That's correct.
Q Okay.
MR. O'CONNOR: Belated objection to the form of the question.

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BY MS. DALY:
Q You talk about the changes to the G2X cap, and I want to know what your opinion is on the chamfer design in the G2X compared to the G2.
MR. O'CONNOR: You can refer to your report, too, it's in there.
BY MS. DALY:
Q Sure.
A In my opinion, the chamfer was changed very little in going from the G2 to the G2X, and the reason is that although the cap was bead blasted, the chamfer area was masked during the bead blasting and as a consequence of that, the bead blasting would not have broken the sharp edges, which are the -- the problem that is associated with the chamfer. And this is contrary to Dr. Fasching's claim that the bead blasting would have softened that particular sharp edge.
The next point is that after the bead blasting, there was a process of tumbling the cap in a bed of ceramic particles, and that would have removed some material by a process of pol- -- essentially polishing, mechanical polishing, but in my assessment it would not have removed a great deal of material and, therefore, would not have

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changed the shape of the chamfer very much.
And as information that's consistent with that, we can look at Figure -- Figure 187 in Dr. Fasching's report, which the report dated May 11 of 2017, where it can be seen that there are two rounded edges at the bottom of the cap; one of them is very gradual, which is the one on the outside, and my assessment is that that edge was broken by the bead blasting; whereas the one on the inside of the cap adjacent to the limb you can see is much sharper in the sense that the radius of curvature is much smaller than the other curved surface.
And I did an estimate of the radius of curvature and I found that the radius of curvature for that chamfer is about 20 microns. Now, I would defer to those who measure the -- the radius of curvature directly in images on the electron microscope and so on, so I'm not going to say this is a definitive measure of the radius of curvature, but it leaves me with the impression that the radius of curvature is about 20 microns. And the radius of curvature that was measured by Dr. Fasching on a Recovery filter quite some time ago was 15 microns.
And so it's my inference that there was

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not a big change to the radius of curvature of the chamfer in the processes that were used in the manufacture of the G2X. And that, therefore, the strain concentration which would be associated with that chamfer was not reduced significantly, although if some material was removed, it would have reduced the strain concentration to some extent.
Q Okay. So, first of all, let me start with that last thing first. You have not done any specific modeling or FEA to determine what the change in chamfer that you're willing to say occurred to this 20 millimeters -- microns, would -- what that impact would be on fracture resistance? You have not done any of that work specifically?
A Well, I've -- I've considered the difference between a radius of curvature of 5 microns and one in which, if you like, the radius of curvature is very large, but in between -- which spans the range from a radius of curvature of 5 microns to ones which are much larger. But other than that, I've not done a specific calculation.
But I should point out that the reduction is proportional to the degree of change of the

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radius of curvature, so if you don't change the radius of the curvature very much, you're not going to change the strain concentration very much.
Q What's the largest curvature that you've looked at to see how that would impact strain?
A You mean what's the largest curvature I've considered?
Q Yeah. I thought you said that you looked at a range and there was a large one that you looked at.
A Well, infinity would be the answer, which of course is not --
Q Well --
A -- not a reasonable answer in the sense that it's not practical for a filter.
Q Did you actually model something on the order of 40 microns, 50 microns, something like that?
A No, what I modeled was a case where the chamfer is having no effect on raising the strains at the -- in the arms where the arms are in contact with the chamfer.
Q Okay.
A And that means that the radius of curvature is -- is just very large.

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Q Do you know from any SEM work that either Dr. Fasching has presented or Dr. Richie has presented whether the arms of G2Xs ever touch the chamfer?
A Did you say SEM work?
Q Yeah.
A Well, I have not seen that work specifically, but as I look at these images it looks as if there is contact between the chamfer and the arms. Although, again, I would not claim that that's a definitive interpretation of the situation. But there are many images throughout Dr. Fasching's report and Dr. Richie's reports where you can see that there seems to be direct contact between the chamfer and the -- the limb and that -- that that contact seems to occur in several of the filters that they looked at.
Q How about G2Xs?
A This is --
Q And just to be clear, are you aware that they've seen very few G2Xs --
A That's --
Q I think two.
A Yeah, that's what I was going to comment on, that there's -- there's -- I'm not even sure,

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to my recollection, that there's a G2X looked at in -- in this report or in Dr. Richie's report other than the exemplar, so there's very little information to go on in that regard.
Q And did you see an exemplar G2X?
A I have an exemplar that I have in my possession.
Q Okay. And have you done any bench testing of that exemplar to see if you can cause wires to touch the chamfer?
A No.
MR. O'CONNOR: Form and foundation.
THE WITNESS: No.
BY MS. DALY:
Q Were there any modifications to Bard's retrievable filters starting with the G2 that did not go forward into the next model until the Denali, which you and I know is quite different?
MR. O'CONNOR: Form and foundation.
THE WITNESS: There -- there may have been slight changes to the lengths of limbs, but other than that, I believe all of the modifications went forward until the Meridian.
MR. O'CONNOR: Are you done with the Fasching report?

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THE WITNESS: Yes.
MR. O'CONNOR: Keep your report in front of you and refer to it if you need to, please.
BY MS. DALY:
Q Now, you have not examined an exemplar Meridian, correct?
A Yes, I have a Meridian in my possession.
Q Okay. When did you get that?
A Oh, a week or two ago.
Q Okay. Because I noticed it was not in your report at that time --
A Right. Right.
Q -- you did not have the Meridian. So from what source did you get a Meridian?
A I asked for it from the plaintiffs' counsel.
Q And what about a Denali, do you have that?
A I have a Denali.
Q When did you get that?
A About two weeks ago as well.
Q Do you know why you didn't get it before two weeks ago?
MR. O'CONNOR: Form.
THE WITNESS: Because I didn't ask for it.
BY MS. DALY:

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Q Okay. So at the time that you wrote all of these reports that we've marked as 2, 3 and 4, you did not ask for those filters?
A That's right. But they -- they were not -- seeing them was not relevant to my opinions in the case.
Q So you're not going to rely on the exemplars?
A No. No.
Q Okay. Have you talked to Dr. Richie about the exemplars or his examination of the exemplars?
A Well, I've looked at his report, but I've not talked directly with him about his examination of them.
Q Do you know if he has them?
A You mean -- sorry, my exemplars?
Q Do you know if Dr. Richie has exemplars of them?
MR. O'CONNOR: Form and foundation.
THE WITNESS: I would need to look at Dr. Richie's report to see what exemplars --
BY MS. DALY:
Q Well --
A -- are included in that report.
Q I deposed him June 9 and he complained he

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didn't have them at that time. So you don't know?
A I don't know.
MR. O'CONNOR: Form.
BY MS. DALY:
Q Having looked at the Denali filter, you do see that there are some differences in that filter than the previous ones, true?
A Yes, that's correct.
Q Okay. Is it your opinion that Bard has failed to reduce as far as reasonably practicable by taking adequate protection measures risks of tilt, perforation, fracture and migration in the Denali?
A Yes.
Q And what's the basis for that?
A Because you still see incidences of all of those phenomena in Denali filters.
Q We'll -- we'll talk about that further later.
You have not undertaken to compare reported rates or reported incidents, let's put it that way, reported numbers of incidents of any of the complications you've identified in the various ones of the Bard filter models, have you?
A No, I have not done that.

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Q Okay. Have you read the clinical trial that was done by -- authored by Dr. Stavropoulous on the Denali filters that was published in 2016?
MR. O'CONNOR: Form and foundation.
THE WITNESS: Yes, I've read the paper and the Bard report on that.
BY MS. DALY:
Q Okay. And do you recall that this Denali trial had 200 patients in it?
A I would need to see the document before I could --
Q Sure.
A -- answer that question.
Q We're going to mark this 12.
(Whereupon, Deposition Exhibit 12 was marked for identification by the Court Reporter.)
BY MS. DALY:
Q And my question for you is: Do you see it was 200 patients and it went for about a period of two years?
A Yes, there are 200 patients.
Q And do you know that they reported no fractures?
A I see that in the abstract it says that

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they reported no fractures.
Q Okay. All right. Now, going back to your report, your report Exhibit 2, again we're back at page 5, Section 3.2.1, paragraph 3 there that goes on to page 6 says --
MR. O'CONNOR: Sorry, where are we looking at? I apologize.
MS. DALY: His MDL report. It's Exhibit 2.
MR. O'CONNOR: You're going to page 6?
MS. DALY: Yeah. Well, the bottom of 5.
MR. O'CONNOR: Thank you.
MS. DALY: To top.
Q It says "Medical devices should achieve the performance intended by the manufacturer and be designed and manufactured in such a way that during normal condition of use they are suitable for their intended purpose."
Do you see that?
A I see that.
Q Okay. How do you interpret that statement by that standard?
A Well, that when -- when the manufactured device is used, that its functionality should be consistent with the purpose of the device.

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Q Okay. In paragraph 1 of the standards that you quoted back on the previous page, that im- -- that standard carries with it the understanding, does it not, that medical devices carry risks?
MR. O'CONNOR: Form. Foundation.
THE WITNESS: Can you specify the line where that is.
BY MS. DALY:
Q Sure. Where it --
A The second to last line --
Q Yeah.
A -- it says -- it says "Provided that any risk which may be associated with their use constitute acceptable risks" --
Q Right.
A -- "when weighed against the benefits." So yes.
Q Okay. So there is not in these GHTF standards that you've quoted any standard saying that a medical device must have no risks associated with it, true?
MR. O'CONNOR: Form.
THE WITNESS: Not to my knowledge is there any such specification.

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BY MS. DALY:
Q And you're not aware of any standard, are you, that says that implantable medical devices must be risk free?
A I'm not aware of any such --
MR. O'CONNOR: Form.
THE WITNESS: -- rule or regulation.
BY MS. DALY:
Q And are you aware of any implantable medical device that is 100 percent risk free?
MR. O'CONNOR: Form. Foundation.
THE WITNESS: I don't have enough knowledge of medical implants as a whole to be able to answer that question.
BY MS. DALY:
Q Okay. Now, going back to that paragraph 3, it -- it speaks in terms of the device being managed -- being manufactured in such a way that during normal conditions of use. You see that language?
A Yes.
Q What is normal conditions of use with respect to what this standard is?
A I would say normal conditions of use are conditions that would be experienced by a very

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large fraction of the population of patients that receive the device.
Q Is there any definition that you're aware of in the standard that that's what they mean when they say "during normal conditions of use"?
A I -- I -- I'm not aware of such specific definition.
Q Okay. Are you aware of any standard for medical devices that says that normal condition of use is a wide range of uses or patient populations or anything?
MR. O'CONNOR: Form and foundation.
THE WITNESS: I'm not aware of any specific regulation in that regard.
BY MS. DALY:
Q If you look at page 6, paragraph 6, where you've quoted to the standard, it says "All known and foreseeable risk" -- "risks and any undesirable effects should be minimized and be acceptable when weighed against the benefits of the intended performance of the medical devices during normal conditions of use."
Do you see that?
A I see that.
Q Are tilt, perforation, migration and

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fracture known and foreseeable risks of IVC filters?
A Of many IVC filters, yes.
Q And are you aware that some of those events have undesirable effects on the patient and some don't?
MR. O'CONNOR: Form.
THE WITNESS: Well, I'm not a medical expert so I can't really answer that question.
BY MS. DALY:
Q Fair enough.
And similarly, as an -- as an engineer, you're not qualified to give an opinion as to what the benefits are of any -- to any given patient of the use of an IVC filter, true?
MR. O'CONNOR: Form.
THE WITNESS: No, I would not do that. I would not offer such opinions on the benefits.
BY MS. DALY:
Q Okay. Are you giving any opinions in this litigation that Bard complied with or failed to comply with any specific FDA regulations?
A No, I'm not offering such opinions.
Q If you look at page 10 of the report you're looking at now, you say that "Bard was not

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frank and honest with the FDA and did not fully inform the FDA of deficiencies in the G2 filter."
Do you see that? It's at the very last long sentence at the bottom of 10.
A Yes. I see that.
Q What's the basis for your opinion?
A The basis, I'm relying on Dr. Parisian for that opinion.
Q Okay. You have not reviewed the materials that she has reviewed, for example, true?
A I've not reviewed --
MR. O'CONNOR: Form.
THE WITNESS: -- all of that material. I probably have seen some of it.
BY MS. DALY:
Q And to your point a moment ago that you are not giving opinions about FDA regulations, is it also fair to say that you are not giving opinions about what Bard's corporate behavior was vis-a-vis what was expected by the FDA?
A I'm --
MR. O'CONNOR: Form.
THE WITNESS: I'm not offering such opinion. Although may I go back and add to my answer to your previous question --

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BY MS. DALY:
Q Of course.
A -- which is that in a couple of situations, I've identified information that Bard gave to the FDA which was not correct, was not information that they should have provided as credible information; for example, the claim that the G2 was 12 times better than the Recovery in terms of its fatigue performance and, also, at the same stage when the 510(k) was being undertaken for the G2, they represented calculations that they did that were irrelevant to fatigue as being -- should I stop?
MR. O'CONNOR: No. Finish your answer.
THE WITNESS: Oh.
So they -- they represented calculations that were not done for fatigue situations which were in fact done to estimate the strains upon implantation of the filter into the vena cava. They represented those calculations as ones that could be used to understand or -- or represent fatigue behavior of the filter, and they also represented those calculations as being experimental tests that would validate the fatigue performance of the G2.

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So in my view, this information was at the very least misleading.
MR. O'CONNOR: Okay. Hold on a second. Excuse me. What was ringing?
THE COURT REPORTER: Sorry.
MR. O'CONNOR: Thank you.
BY MS. DALY:
Q So I appreciate that answer. My question is: Are you going to take it the next step and give the opinion that the intention of Bard was to be not frank and not honest with the FDA?
MR. O'CONNOR: Form.
THE WITNESS: I -- I will not interpret those actions in that way but, instead, rely on Dr. Parisian for the overall assessment of that situation.
BY MS. DALY:
Q All right. Thank you.
And I guess one other question I have there is: Do you have any idea what the FDA did with the information that you've just described for us that Bard gave them about the G2? Do you know what they -- if they relied on it, if they asked questions about it, if they rejected it? Do you know?

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MR. O'CONNOR: Form.
THE WITNESS: Well, I know that because of some reports of contacts, reports with -- with the FDA, that these points were -- well, the matter of the 12 times better fatigue performance was -- was discussed with the FDA.
BY MS. DALY:
Q Okay. Your report that we're on now, back at page 6, Section 3.2.2.2, it's entitled "FDA Mandated Quality System Regulation Design Controls." And you just -- you cite to some of those regs, correct?
A Correct.
Q And then in 3.2 -- 3.2.2.1 you talk about the class of devices that those -- the design controls relate to, correct?
A Correct.
Q In citing this section or including this section, are you providing any opinion that Bard failed to comply with FDA regulations as they relate to design controls, quality systems, design validation, design output or verification that are listed on pages 6 and 7 of your report?
MR. O'CONNOR: Form.
THE WITNESS: No, I'm not offering any such opinion.
BY MS. DALY:
Q All right. Let's look at page 9 of that report where you start talking about the G2. I'm going to talk about arm strain issues first. Okay?
A Okay.
Q What types of analyses did you perform to estimate strains on any of the Bard IVC filter arms?
A I carried out calculations that were done by what is called Euler-Bernoulli beam theory, and I also carried out some finite element calculations of some of the -- the filter limbs.
Q And what were the principal assumptions that you incorporated when you did your calculations and/or FEAs about the Bard filter arms?
A In the F- -- FEA?
Q Either remodeling or --
A Either --
Q -- in the FEA.
A Yeah.
Q For example, I know that you assumed that the vessel arm had perforated or endothelialized in the vessel?

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A In some calculations I assumed that that was the case, yes.
Q Okay. What else?
A And I assumed that it had -- the -- the arm had endothelialized to the wall of the vena cava.
Q And when you say that, are you saying it's like setting rebar in concrete type of endothelialization or that there's some allowable movement --
A Well --
Q -- considered in your calculations?
A I'm only saying that the tissue grows in such a way that it glues the arm to the wall of the vena cava.
Q And that's what I'm saying. When you say "glue," to what extent is the arm then unavailable -- unable to move, in your analysis?
A Well, in my analysis it is constrained from experiencing rotating at the location where it --
Q Okay.
A -- is glued to the wall of the vena cava.
Q All right. So do you also assume that vessel motion is unaffected by the presence of the

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filter in your calculations?
A Yes.
Q Okay. And you also assume that the vessel is stiff enough to prevent rotation at the tip of the filter --
A Well --
Q -- is that right?
A -- assume that the vessel and the surrounding tissue and organs are stiff enough to constrain that rotation, not just the wall of the vena cava itself.
Q It's the combination?
A It's the combination.
Q And you assumed for purposes of some of your arm calculations that there was linear elastic material behavior?
A I assumed that that was the behavior because that is the behavior that the arm will experience in the circumstances -- in certain of the circumstances involved.
Q And your analysis on arm strain there was involving a single arm?
A Correct.
Q Did you do the same kind of analysis on a leg, something that had the design dimensions or

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characteristics of the leg?
A Well, I did some calculations of the behavior of a leg which is hit by a clot.
Q Right. But not the kind of thing where you're constraining the leg, gluing it?
A Well, yes, the constraining of the leg was involved in that calculation as well.
Q Of the clot?
A Of the clot arriving at the leg and -- but what I have not done is calculations where I look at the leg response to the expansion and contraction of the vena cava.
Q Okay. That's -- thank you.
So what you did not do was to take your analysis of the arm that we've just talked about and expand that to be an analysis of all arms?
MR. O'CONNOR: Form.
THE WITNESS: Well, it is in fact an analysis of all arms because the symmetry of the filter, as long as it remains in its designed shape, the symmetry of the filter and the assumption that the vena cava itself is symmetric around the filter, ensures that all of the arms will behave in the same way under the expansion and contraction of the wall of the vena cava.

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BY MS. DALY:
Q What if others of the arms are not endothelialized to the point that they are basically glued, have you modeled anything like that?
A I've not modeled that, no.
Q Okay. And the same question with the leg analysis that you did, you did not take it further and look at what would -- what strains would be on any of the legs of a filter if you assumed all six legs, one of them in the glued position and the other ones in other conditions?
MR. O'CONNOR: Form.
THE WITNESS: Yes, I have not done a calculation in which one of the legs is -- is under different circumstances from the others.
BY MS. DALY:
Q Okay. One or more?
A One or more, yes.
Q Yeah. Okay.
What structures in the body are sufficient to contribute to the -- are sufficient to work with the vena cava itself to prevent rotation at the tip?
A Well --

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MR. O'CONNOR: Form.
THE WITNESS: -- there's vertebra near the vena cava.
BY MS. DALY:
Q Okay.
A And --
Q What else?
A -- there are some muscles which are quite close to the vena cava, and so that it's -- it's feasible that they could enforce that -- they're stiff enough to enforce enough constraint to limit the rotation of the -- of the limb of the vena cava.
Q How about perforation --
A Of the limb of the filter. Sorry. Excuse me.
Q How about perforation of some other -- of a strut to a duodenum?
A Well, I'm uncertain as to whether that would have sufficient effect.
Q How about to a vessel?
A But can I --
Q Of course.
A -- continue my answer?
Q Of course.

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A Which is that the duodenum does have some muscle around its perimeter, so there are some muscle structures associated with the duodenum. But I'm unsure whether that is going to be stiff enough to have the effect that you're addressing.
Q Okay. What about a perforating strut to a vessel such as the aorta, an iliac artery, a renal vein?
A I don't have an assessment of the impact of -- of those organs.
Q Okay. What is the typical stiffness, if you know, of either vertebra or muscle in the area around the vena cava?
A Well, Dr. Briant gives values for that, so it would be easiest to refer to his report to get those stiffnesses.
Q Do you have any criticisms of what he used in that regard?
A I don't have criticisms of the values that he used in the -- for the modulii of the various materials.
MR. O'CONNOR: Is it warm in here?
(Brief discussion off the record.)
BY MS. DALY:
Q So your assumption that the vessel

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prevented rotation and is maintained in the same motion as it did prior to filter implat- -- implantation is an assumption you made in your analysis in this case?
A Sorry, can you repeat the question.
Q Yeah.
You made an assumption that went into your calculations in this case that the vessel was prevented from rotating under the condition that you modeled and it maintained -- the vessel maintained the same motion as it did prior to filter implantation?
A That's correct.
Q Okay. Did you perform any calculations to justify those assumptions?
A Well, I didn't perform any calculations but I've looked at some information that's in the scientific literature and it's -- it's contained in one of the papers that I brought today. And if I --
Q Yeah, you show me that --
A -- find that.
Q -- and I'll put a number on it.
Is it this one that I took away from you?
A No, it's not that one. No.

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Q Okay.
A It's this paper here.
Q All right. We're going to mark as 13 the Laborda Kuo paper entitled "Respiratory-Induced Haemodynamic Changes: A Contributing Factor to IVC Filter Penetration," and its publication date is March 2015.
(Whereupon, Deposition Exhibit 13 was marked for identification by the Court Reporter.)
BY MS. DALY:
Q Let me get that out of my pile and catch up with you.
MR. O'CONNOR: Thank you.
BY MS. DALY:
Q All right. So tell me what in this paper you rely on for what we were just talking about.
A Well, I -- I rely on the author's measurements of the area reduction of the vena cava during Valsalva that they measured in a number of patients, and I've forgotten how many patients, 101 patients that they measured this -- these -- this reduction in area in. And --
Q Where is that on the --
A It's -- it's summarized on -- in Table 2

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on page -- well, I'm not sure if your copy has page numbers but --
Q It does.
A Okay. 1195.
Q Okay.
A And at the top you'll see that there's Table 2.
Q Yes.
A And what they did was they measured the area reduction in the vena cava during Valsalva --
Q Uh-huh.
A -- and they did it in patients who had received either a Cook Celect or a Cook Tulip filter, and they found that where the filter was located, the area reduction of the vena cava was 6- -- on average, 62.55 percent. And what they found is that elsewhere than where the filter is, namely 3 centimeters above the filter and 3 centimeters below the filter, they found that the area reduction was -- was 90 percent.
And so what that indicates is that the -- in the case of the Tulip and the -- the Celect filter, the filter is resisting the area reduction of the vena cava but only to the extent of making the area reduction about two-thirds of the area

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reduction when the filter is not present. Now, there's other information which is -- I need to identify it, but I think if you go to page 1194 --

Q Okay.

A -- and the right-hand column under the Results section.

Q Uh-huh.

A And if you go to the -- one, two, three, four, five -- the fifth paragraph which starts "In four patients with major filter penetration," you see that in -- it's actually in 23 patients because there were four with major penetration and 19 with minor penetration.

Q Uh-huh.

A And, therefore, at least 23 patients they found that the area reduction of the vena cava was 71.93 percent on average.

And I interpret this to be the worst case in the sense that of the patients who had filters, the ones who had penetrated filters were experiencing the greatest reduction at the filter of the area of the vena cava, and what this means is that the area of the vena cava after Valsalva or as a consequence of Valsalva is about 28 percent of its area before the Valsalva event takes place. So

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it's a very big reduction in the area of the cross-section of the vena cava even although the filter is present.

Q And what does that mean with respect to strains on the filter?

A I didn't estimate the level of strains in the filter, and I can come to that in -- in a second when I go through my summary of the situation, because I would like to present that information specifically in terms of -- of the Bard filter rather than the Cook filter.

But I suppose, to be responsive to your question, I would say that it means that there's a very large strain would be developed in the Celect filter as a consequence of the reduction of area which was involved.

Q Okay. So the reduction of the area is connected to the Valsalva?

A Yes.

Q Okay. And this study shows that in Celect and Tulip filters, that with -- with no perforation being taken into consideration, let's look back on 1195 --

A So --

Q -- with all patients --

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A Yes, all patients was perforating --

Q Perforating or not perforating

A Yes. Correct.

Q Okay. After -- from the Valsalva event, for these Celect and Tulip filters, there was the filter resisting -- putting resistance up to the reduction?

A Correct.

Q Okay. Of two-thirds?

A Well --

Q Approximately 60-some percent?

A Essentially, the area reduction was two-thirds of what it would be without the filter, so, in other words, whereas when the filter was not there, the area went down to about 11 percent of its original area. With the filter's present, on average it went down to 37 percent or thereabouts.

Q Meaning that in Valsalva there's less of a contraction/expansion --

A There's --

Q -- with the filter in place?

A That's correct, yes.

Q All right. So take me back to 11- -- the page before that, 1194, so I understand what you're saying there. So then they looked at 23 patients

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who had penetration, and do we know what they're saying -- what they mean when they're saying -- they say "Four patients had major filter penetration and nine had minor filter penetration"? Do we know what their --

A I don't know what their definition of --

Q Okay.

A -- "major" and "minor" is. My only -- my only reason for identifying that is that it was a subset of the -- of -- of the cohort and it has a worst -- worst case in terms of how much reduction was involved compared to the cohort as a whole.

Q Okay. So with the penetrating ones, forget how much they are because we don't really know.

A Right.

Q With the penetrating ones in the Celect and Tulip filters, in Valsalva there was also a limitation to the contraction and expansion that was seen when filters were in place?

A That's correct.

Q All right.

A So now instead of reducing to 10 percent of the original area, it goes down to 28 percent of the original area.

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Q Okay. Now, look at the last sentence in that paragraph that you pointed out that begins "In four patients." The last sentence says "Penetration was not significantly related to venous pressure increase."

Do you know what they meant by that?

A Well, in the paper, they measure the increase of the pressure during Valsalva, and I'm not exactly sure what they mean but they -- they obviously found that the venous pressure didn't matter to the penetration which was involved -- which they observed in the -- in the cohort. But I'm not --

Q Yeah.

A -- I should say I'm not exactly sure what they mean by this.

Q The way I read it is that the venous pressures that they read on all patients were -- were about the same whether you had penetration or you didn't.

A I guess so, yes.

Q Okay.

A I'm not sure if that's what it means, but that's a reasonable interpretation.

Q And what we also don't know from this

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paragraph is what the differences were in the reduction of the cross- -- what do we call that?

A Cross-sectional.

Q Cross-sectional, we don't know what the cross-sectional reduction was keyed to whether you had multiple perforations at 5 millimeters or you had two perforations at 3 millimeters, there's no information?

MR. O'CONNOR: Form.

THE WITNESS: Well, there's no information on that, but that's not relevant to my assessment of -- of this information.

BY MS. DALY:

Q Okay. So why is this information important to you as you relate it to the Bard filters?

A Okay. So Celect filters and Tulip filters are significantly stiffer than Bard filters. Perhaps the limb of a Celect filter is perhaps 10 times the stiffness of -- of a Bard filter, and that's only based on public information that is available by measuring the diameter of a filter and knowing the material which -- which is present in the filters.

So the Celect and the Tulip filters are

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stiffer than the Bard filters, which means they would resist the reduction in area more than the Bard filter. So I deduce from that that the reduction in area when the Bard filter is present in these 23 patients that have the larger area reduction would see an even bigger reduction in area than was observed when the Celect or Tulip filter was present.

And it's my assessment that the area reduction could even approach the 90 percent that was observed in the absence of the filter because of that difference in stiffness of the -- of the filters involved.

Q Meaning with the Bard filters, you would expect a present Bard filter to put up some resistance to the reduction that Valsalva is causing?

A Correct.

MR. O'CONNOR: Form.

BY MS. DALY:

Q But your deduction is that it could be as little as 90 percent?

A Well, no, that's not quite what I said.

Q Okay.

A What I said is that the resistance could

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be so small that the reduction in area would be almost 90 percent, very similar to what is observed when the filter is not present.

Q Okay. So what have you done insofar as modeling or FEAs to confirm your deduction that the resistance with the Bard filters in place could be very small?

A I didn't do finite element analysis, I just made that estimate that the stiffness is perhaps five times greater in the case of the Celect filter compared to the Bard filter and that, therefore, when the Bard filter is there, the reduction in area is going to be more than when the Celect filter is there.

Q And where are your calculations that show my calculations and what assumptions I used for Celect, Tulip, and what assumptions I used for Bard in that regard?

A I didn't --

MR. O'CONNOR: Form.

THE WITNESS: I didn't bring them with me.

Q Do you have that?

A Yes.

Q Can you send it to Mark so he can send it to me?

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A Yes, I can do that.
Q All right.
A But I need to continue with my information.
Q Oh, yeah, keep going.
A So now if I could have a copy of Dr. Briant's report. Do you have one available?
Q Hmmm. I don't know that I do.
A Well, I can do it without reference to his report.
MR. O'CONNOR: Let's see if you have the report.
MS. DALY: I do not.
Q You mean his general MDL one? I do not have --
A Yes.
Q I do not have that with me.
A Okay. So he does calculations in which he has his model of the physiology surrounding the vena cava.
Q Uh-huh.
A And he imposes displacement, I'm referring specifically to Configuration 3 where he is modeling Valsalva --
Q Okay.

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MR. O'CONNOR: Here, I got a copy of the report.
MS. DALY: Okay. Good. Let's let him look at that. Give us a page.
MR. O'CONNOR: Which report are you looking at? Which report are you referring to?
THE WITNESS: It's -- I'd need to look at it before I can say which one it is.
BY MS. DALY:
Q And while he's looking for that, what you're about to say about Briant's report is not in your rebuttal report, this is new?
A This is new -- that's correct, it's new.
Q Okay.
MS. DALY: I'm not saying that's okay, to your lawyer --
THE WITNESS: No, but --
MS. DALY: Hold on one second.
Mark, I'm not saying it's not necessarily true -- okay, we're going to talk about it, but I think he was supposed to put everything in his rebuttal.
MR. O'CONNOR: Well, I think he's covered --
MS. DALY: Go ahead.

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MR. O'CONNOR: I think he's covered this area in his rebuttal report.
MS. DALY: Well, we'll argue about that later.
THE VIDEOGRAPHER: Excuse me, Counsel, your microphone, when you get a chance. Sorry to interrupt.
THE WITNESS: So --
BY MS. DALY:
Q So take me to a page, would be great.
A So -- yes.
Q All right.
A In this fashion, page 33.
Q Okay.
A Just before Section 4.3.2.
Q All right.
A And you see that these are -- there's a Figure 23 --
Q Okay.
A -- in which modeling of the Valsalva processes is -- is undertaken.
Q Okay.
A And Dr. Briant presents his results, which are in blue, and my results, which are in red, where I assume that the filter does not restrict

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the contraction of the vena cava at all.
Q Uh-huh.
A And you observe in the case where the reduction -- the nominal reduction is 50 percent, that my results are about 10 times larger than his. Now, there's an adjustment that should be made because, as you've referred to, I assume no rotation of the -- of the arm where it intersects the vena cava wall.
Q Uh-huh.
A Which will essentially double the strains that I compute. So if -- if we take that out of the picture, then we have strains in my case which are about five times the strains that -- that he calculates.
Q Okay.
A Now, what that indicates is that the deflection of the arm is about -- in his case, is about one-fifth of the deflection of the arm in my case, which means that the reduction in area of the vena cava where the filter is -- is present would only be about one-fifth of the reduction in area of the vena cava in the absence of the filter.
Q Okay.
A But as we've -- I've already pointed out,

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that in the experimental data, the reduction in area should be much more like three-quarters or even 80 percent where the filter is present compared to where the filter is not present.
Q And how would that change his blue versus your red?
A Well, his -- it would bring his blue up to halfway up my red because I'm discounting the constraint on rotation --
Q Okay.
A -- when making that comparison, to try and make it as a direct comparison as possible.
Q And are you -- in telling me this now, are you taking into consideration what you've just previously told me, that you think that the Bard filter in place has a small resistance, somewhere on the order of 10 percent?
A Yes.
MR. O'CONNOR: Form.
THE WITNESS: When I said that the results would come up to halfway along my red results, that assumes that the Bard filter has no resistance relative to contraction of the vena cava. If I take the other result, which is that its resistance would reduce the area reduction to two-thirds, that

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would still bring you up to a third of -- of the way up my red mark; in other words, deflections and strains which are much bigger than Dr. Briant has calculated.
BY MS. DALY:
Q Okay. And then what you have not done with what you just discussed with me, you haven't done an FEA specific to that issue, true?
A I haven't done FEA, but I've done all the Bernoulli calculations which are specific to that situation and which relax the rotation constraint. And that's -- that is mentioned in the report where I comment that the rotation constraint approximately doubles the strains which are involved.
Q And are you aware of any medical literature that looks at Bard filters for its impact on resistance to expansion as was done by Laborda with the Celect and Tulip filter?
A I haven't seen any such data or papers.
Q And you haven't tried to recreate that in a test yourself?
A No.
MR. O'CONNOR: Form.
BY MS. DALY:

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Q All right.
A When you say "a test," you mean --
Q Like a bench test.
A Not in a bench test, no.
Q And --
A Or even --
Q -- do we even know how we would do that?
A -- in a clinical test.
Q How would we do that in a bench test?
A I think I know how to do it but I don't --
Q You haven't developed one yet?
A Yes. Exactly.
Q Okay.
MR. O'CONNOR: But were you done with your answer? You were saying -- did you do something else? I didn't follow your answer.
THE WITNESS: Sorry, which answer are you --
BY MS. DALY:
Q I thought you answered to me what --
THE WITNESS: Which answer are you referring to?
MR. O'CONNOR: Just continue.
THE WITNESS: Okay.
BY MS. DALY:

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Q Okay. Is there anything else you wanted to say from Dr. Briant's report about the topic we're on?
A About the which?
Q Topic that we're on right now?
A Well, all I want to say is that this deduction tells me that my assumptions are much closer to being relevant to what really happens in the vena cava, both during normal breathing and during Valsalva, than the assumptions that Dr. Briant has made. And it's my deduction from that that what he should have done to make it more realistic would have been to impose the displacement constraints much closer to the vena cava than he actually did; in other words, instead of having the physiological model of the surroundings go out to --
MR. O'CONNOR: That's mine.
THE WITNESS: Oh, sorry.
MR. O'CONNOR: That has my notes on it.
MS. DALY: That's all right. He can talk from it, I won't look at your notes.
THE WITNESS: So instead of the physiological model going out to 1 inch away from the vena cava, it would have been more realistic to

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impose the displacement constraints closer to the vena cava. I'm not sure where, but closer than the 1 inch that he assumed in his calculation.
BY MS. DALY:
Q But you agree that there has been no bench testing done by either you or Dr. Briant to verify what you've done with modeling, true?
A Could you repeat the question.
Q There has been no bench testing done under any protocol by either you or Dr. Briant to try to verify what you modeled?
MR. O'CONNOR: Form.
THE WITNESS: You mean --
BY MS. DALY:
Q On this issue. On this issue
A -- this specific issue?
Q Yes, sir.
A No, I agree. No.
Q Okay. And you are not aware of any clinical work that's been done looking at a Bard filter in a patient in Valsalva to try to look at this -- to try to gain the same data that Laborda got in the Celect/Tulip study?
A I'm not aware of any such paper or data.
Q Okay.

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MR. O'CONNOR: Are you done with that?
THE WITNESS: May I just add one thing, which is -- and perhaps I wasn't finished with the answer that was -- which is that since the boundary conditions I used are much closer to being realistic in my opinion, it means that the strain amplitudes that I computed are more -- are more realistic in terms of representing what will happen both during normal breathing and during Valsalva. Although, I would say that there's still the question of the rotation which could be debated in terms of what that will do to the strain levels involved.
But I've assumed that as a worst case, which is almays -- always my concern when I make the assumptions about how to do the calculations.
BY MS. DALY:
Q Do you retain -- do you routinely assume a linear elastic constitutive response for nitinol --
A I --
Q -- in your analysis for companies during device development relating to nitinol products?
A Well, yes, when the response that is being investigated is in the linear elastic regime, I use a linear elastic model for the behavior of the

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nitinol.
Q Have you submitted fatigue strain analyses for any medical device submission or consulting work where you only did analyses that included linear elastic calculations?
A Well, the -- yes, in the sense that the linear elastic calculations were presented in parallel with calculations that were done using nonlinear nitinol constitutive laws as well.
Q At page 53 of your report, it's the last paragraph I wanted to ask you about, it says "The analysis just described requires follow-up by more detailed exploration by FEA as it shows that cyclic strains are potentially dangerously high."
Do you see that?
A I see that.
Q And what does that relate to? Which -- which -- which of the analyses is that relating to?
A Well, the analyses that it relates to would be those strain ranges in my calculations that fall outside of the linear elastic range because that requires a nonlinear analysis to carry it out. But I should say that where those strain levels are that high, then you're already looking at worrisome levels of strain.

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Q And have you done any more detailed exploration by FEA of that issue?
A Not of that issue, no.
Q Okay. You state there that the cyclic strains are potentially dangerously high. That was your term?
A Yes.
Q Does your analysis show what the potential high strains are?
A Could you repeat that question and possibly clarify.
Q Yeah.
Does your analysis show what the potential high strains are, the range of potential high strains are, in that particular analysis where you're saying the cyclic strains are potentially dangerously high?
A Can you --
Q Yeah, it's that same sentence at the bottom -- bottom paragraph of 53, first sentence. You're talking about the analysis --
A Okay. So --
Q -- and you say more detailed exploration by FDE -- FEA should -- and then it says "as it shows that the cyclic strains are potentially

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dangerously high." That's what I'm asking about. What does that mean?
A So is this question independent of whether FEA should be done?
Q Yes.
A Is it simply --
Q Yes. Yes.
A Yes. Okay.
So in the preceding pages, there are a number of results that give you levels of strain at the place where the limb -- where the arm enters the cap and that is where, given my assumptions that the level of strains is highest, and some of those values are in excess of levels that Bard would identify as the fatigue limit of the material.
And, in addition, many of the results are higher than the fatigue limit of similar materials, and in those circumstances one would worry that when -- you're in a danger level because the material similarities and dissimilarities may mean that this is a high enough level of strain to cause fatigue failure of the material.
Q And that was really my question. Your "dangerously" term goes to it might be approaching

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its fatigue --
A Yes, so I --
Q Its fatigue limit?
A That -- so I can clarify precisely my --
Q Okay.
A -- answer, which is that some of these results lie above the fatigue limit that Bard identified --
Q Got it.
A -- for their material.
Q Good. Okay.
A And can I make one more comment, which is that if that situation is modified by the strain concentration, then the level of strains is even higher, and that means that some of these other results which lie below the Bard fatigue limit might rise above the Bard fatigue limit because of the strain concentration.
Q Okay. But again, with respect to those things, there have been no separate FEAs done to verify?
A Well, there's one FEA that we did which confirms the strain levels which I computed by Euler-Bernoulli beam analysis and I've compared the strain levels that are in these tables with results

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that Dr. Briant obtained, adjusting for the different assumptions which went into the calculations, and I find that my results are always consistent with his results in terms of the magnitude of the strains which are predicted.
Q So let's go back to your report, page 9, and we were back on -- we were back on the G2 section.
A Okay.
Q And this initial discussion in paragraph 1 -- I'm sorry, number -- the number 1, not paragraph 1, but go down to where you got --
A Oh, yes.
Q -- the 1.
A Yes.
Q And you're talking about the alternating strain in the arm of the G2?
A So we're talking about paragraph 2 or Section 2 of this?
Q Yes, and I'm talking about the No. 1 --
A Yes.
Q -- that begins "The alternating strain in the arm." Okay. Is it your opinion that the strain in the arm that you're discussing there could be a contributor to fracture or is that also

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relating to any of the other complications, migration, perforation or tilt?
A Well, it's -- it's related to fracture. That's its relevance.
Q Okay. In that same No. 1 section, you say that "the arm has fully perforated." What do you mean by the term "fully perforated"?
A I mean that the arms have gone through the vena cava to such an extent that the arms are in their design shape, which is the shape they would be in when the filter is simply sitting on the table in front of us.
Q So it would -- how far they're out would depend on the diameter of the vena cava of the person?
A That's correct.
Q All right. With what frequency does a full perforation like that occur in patients that have Bard filters?
MR. O'CONNOR: Form and foundation.
THE WITNESS: I -- I don't know the answer to that.
BY MS. DALY:
Q You're aware of individuals either in the medical literature or in cases that you've seen on

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this litigation who experience no fracture but have perforations of different kinds, true?
A Yes. Correct.
Q Tilts of different kinds?
A Correct.
Q And even migrations of different kinds?
A Yes.
Q In that -- in that sentence, you make an assumption about the arm having endothelialized by the tissue. We've just talked about what you mean by that, correct?
A Right. Right. Correct.
Q All right. With what frequency does that type of endothelialization, in effect gluing the arm as you modeled it, happen in patients who have IVC filters?
MR. O'CONNOR: Form and foundation.
THE WITNESS: Well, I'm -- I'm not a full expert on that issue, but it's my understanding that almost all of the filters endothelialize eventually to the wall of the vena cava.
BY MS. DALY:
Q To the extent that you modeled it?
A You mean to the extent that it would constrain the rotation?

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Q Yes.
A I don't know the answer to that question.
Q Okay.
A But I should comment that it -- it's not so much whether the wall will directly constrain the rotation as that the interaction of the end of the filter arm, the wall of the vena cava, and the material outside the vena cava, plus the motions which are being imposed on that system, will affect how the arm moves.
Q Right. And there can be thousands, I think Dr. Richie said millions, of permutations of filter condition in a -- in people, fair?
A That's correct.
MR. O'CONNOR: Form.
THE WITNESS: But my -- my assessment is always to find the worst-case condition that is likely to occur.
BY MS. DALY:
Q On any of the worst-case conditions that you have considered in your analyses, with what frequency does that set of conditions occur in patients with Bard filters?
MR. O'CONNOR: Form and foundation.
THE WITNESS: I don't know.

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MR. O'CONNOR: When you get to a point, can we take a break?
MS. DALY: Sure. I'm heading to page 11. We'll take a break.
MR. O'CONNOR: Oh, okay.
THE WITNESS: The break is now?
MS. DALY: Yes.
THE WITNESS: Okay.
THE VIDEOGRAPHER: This is the end of Media No. 1. We are going off the record at 10:52.
(Recess taken.)
THE VIDEOGRAPHER: This is the beginning of Media No. 2. We are back on the record at 11:06.
BY MS. DALY:
Q Dr. McMeeking, I'm going to start on page 11 of your report, please.
A Okay.
Q And what I wanted to talk about was at this point in your report, you're talking about a model that you were using and that -- that involves a filter arm fully perforating in this model?
A Can you draw me --
Q Yeah, I --
A Draw my attention to a specific line.

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Q Yeah, I'm just -- I'm about to talk about the Murphy paper and the Laborda paper.
A Okay.
Q It's at the top of 11.
A All right. Fine.
Q And so what I think is happening here is you're modeling the filter fully perforating and the endotheli- -- endothelialized arm, correct?
A Correct. That's correct.
Q And then you're -- you're about to talk here or you do talk here about movement of greater than 1 millimeter of the arm?
A Yes.
Q Okay. So let's talk about Murphy for a minute.
A Okay.
(Whereupon, Deposition Exhibits 14 and 15 were marked for identification by the Court Reporter.)
BY MS. DALY:
Q You cite to the Murphy study, and let me go ahead and give you -- I'm going to talk about Laborda too. I've marked as 14 the Murphy study, "Evaluation of Wall Motion and Dynamic Geometry," and as 15 the Laborda "Influence of breathing

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movements and Valsalva maneuver on vena cava dynamics."
A Okay.
Q Okay. So the Murphy paper came out in 2008?
A Correct.
Q Okay. And the Laborda paper that I just handed you was published in 2- -- 2014?
A That's correct.
Q Now, the Laborda paper that we just talked about a few moments ago that related to the Celect and Tulip, when -- when did that paper come out?
A It was published in 2015.
Q Okay. Now, Murphy's study was of a small number of patients and he was looking at what?
A She and her colleagues were looking at the expansion and contraction of the vena cava during normal breathing in supine patients who had been anesthetized for -- yeah.
Q Are you aware of any study similar to Dr. Murphy's study prior to the time that she published that in 2008?
A Well, there -- there are studies by various individuals, I can't name them, but there were studies prior to that using various methods to

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try and establish the expansion and contraction of the wall of the vena cava.
Q And was there any discussion in the Murphy paper about any impact that an in situ IVC filter would have on expansion and contraction of the vena cava during respiration?
A I don't recall. I...
Q These were patients without IVC filters?
A That's correct, they had no filter.
Q Okay. Do you know whether other doctors or scientists agree or have come to the same conclusions that Murphy came to with this small study?
A Well, I recall that prior to this study, there were different values for the expansion and contraction that one would see in the literature. Some of -- some of them smaller than the results in Murphy, et al.
Q Okay. And what did Murphy determine?
A They determined -- may I look at the paper?
Q Yes. Of course.
A They determined that on the short axis of a vena cava which was approximately elliptical, that the expansion and contraction of the diameter

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of the span of the vena cava in some cases was as small as .6 millimeters and was in some cases as big as 1.8 millimeters.
Q Did you use that information in any of your analysis?
A Well, in some of it, yes.
Q And how did you use it?
A I -- I took the 1.8 millimeter expansion and contraction of the diameter and I assumed that that would take place on the span of the -- of the -- the short span of the vena cava with having the smallest span of all those that Murphy, et al. looked at; namely, the -- the short span of the vena cava that they looked at ranged from, well, the standard deviation, so it wasn't necessarily the shortest span. The standard deviation took the diameter down to 10.2 millimeters.
I then assumed the 1.8 millimeter would occur for that 10.2 millimeter diameter vena cava as the worst case that was possible in the combination of results that they obtained, and that gave me an 18 percent reduction in the diameter of the vena cava. And I used that as a worst-case possibility of what would happen during normal breathing in the -- in a patient's vena cava.

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Q Did you take into consideration, in using that number, what the presence of a filter might do to restrict the change in the vena cava by respiration?
A No, I didn't take that into consideration, and for the reasons that we've just discussed. I don't think that is necessary in terms of getting worst-case condition. Yes.
Q And again, what we've already talked about is you've told me what you have done and what you haven't done to determine how much presence of a Bard filter will change the expansion of the vena cava whether under respiration or Valsalva?
A That's correct, but -- but what I'm saying is that if you deduce what are the worst-case conditions, that the filter is not stiff enough to resist the motion of the vena cava, and the combination of data in the Murphy, et al. paper comes out in the way that I described it, then the worst case is that even with the filter, the contraction is 18 percent of the diameter.
Q Have you done any testing of any kind or seen any other clinical testing that looks at the respiration impact in patients who do have a vena cava filter present?

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A Well, there's the paper we discussed by Laborda, et al. that has the study of the patients with Celect and Tulip filters.
Q But that's in Valsalva, right?
A That's in Valsalva.
Q I'm limiting it right now to just regular respiration.
A I haven't seen any studies -- I'm not aware of any studies where there is a filter present and this study -- the equivalent of this study has been carried out.
Q Do you know that Bard was aware of the Murphy study after it came out and considered it in working on their designs?
MR. O'CONNOR: Form.
THE WITNESS: I'm not aware --
MR. O'CONNOR: Foundation.
THE WITNESS: -- of that aspect.
BY MS. DALY:
Q Now, the analysis that you did applying the Murphy paper data resulted in an estimate, if you look down towards the end of that first paragraph, it's about 6 lines -- 7 lines up, and it says "It would suggest that a filter arm experiencing alternating strains of 1.38 percent in

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a 14-millimeter-diameter vena cava" --
A Yes, I see that.
Q -- "would last between 5,000 and 100,000 breaths or between 5.5 hours and 111 hours at 15 breaths a minute."
A Yes.
Q Okay. 111 hours is less than five days, right?
A Correct. Yep.
Q Okay. So how many cases of fracture are you aware of that have been documented to have occurred within 5.5 to 111 hours with Bard filters?
MR. O'CONNOR: Form and foundation.
THE WITNESS: Well, I'm not -- I'm not -- I don't know results like that, but a point to be made is that the clock starts when the full perforation and endothelialization of the filter has been achieved, so it's not a matter of counting the time from the beginning of the filter being implanted in the patient but, rather, the time is counted from when the conditions that I assume have arisen.
BY MS. DALY:
Q And when do those conditions arise?
A It could take quite some time for those

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conditions to arise because tilting and perforation -- well, tilting is not in this assumption, but -- but perforation is progressive and can take some time to develop. It might be a matter of weeks or it might be a matter of -- of -- of a number of years.
Q And you don't know patient to patient how long that takes, true?
A No, I don't.
Q And what degree of perforation are you saying is necessary to start this clock ticking for your analysis of failure in 5.5 to 111 hours?
A Well, in this case the degree of perforation would be the full extent of -- of perforation, so the clock wouldn't start until the filter has achieved its designed shape.
Q Okay. Meaning it's perforated so far through the vena cava of the subject patient that it's regained its full size when it's fully deployed?
A That's correct.
Q How often does that happen in patients?
A I don't know.
Q You assume it doesn't happen in everybody?
MR. O'CONNOR: Form.

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THE WITNESS: I don't have any basis for making any assumption at all.
BY MS. DALY:
Q Okay. One way or the other?
A One way or the other.
Q Okay. Did you do any actual bench testing with a Bard filter or any Bard filter to determine if your assumptions could be verified that perforating struts of the filter to the maximum amount through vena cava tissue would lead to fast failure?
A I did no bench tests of that nature.
Q If the condition that you're talking about with full perforation -- first, let me back up.
When you're talking about the filter getting to the point of having this full perforation, are you talking about one strut? Multiple struts? All struts? What is -- what do you mean?
A Well, it would be at least two struts opposite each other.
Q Okay. On opposite sides?
A Opposite sides.
Q Okay. So the condition starting this fast fracture would not be -- using a clock now, as we

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obviously do with this, if the 12:00 and the 1:00 side by side were doing that, that wouldn't start the clock?
A That wouldn't constitute the condition, no.
Q They have to be on opposite sides, like a 3:00 and a 9:00?
A Correct.
Q All right. And you don't know how often perforation occurs with struts that are in opposition to each other as opposed to side by side, true?
MR. O'CONNOR: Form.
THE WITNESS: I don't know information on that.
BY MS. DALY:
Q You've seen -- you've seen cases where the medical reports are that you've got two struts side by side that might be perforating, true?
A That's correct.
Q Now, Laborda study that was published in 2014, that talks about the Valsalva impact on changes in size of the vena cava, right?
A That's correct.
Q And sort of the precursor of what they

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then applied to the Celect and Tulip?
A That's correct.
Q All right. Were their findings in that paper any different with respect to contraction and expansion of the vena cava than what they found with the Celect filter in place?
A Sorry, could you --
Q Yeah.
A -- repeat that question.
Q Yeah. Let's do it easier.
What did they find was the average expansion and/or contraction of the vena cava under the effect of Valsalva?
A I'm going to read the Results --
Q Sure.
A -- section in the -- in the abstract.
So they give results for the area during neutral breathing and the area during Valsalva.
Q Uh-huh.
A And the ratio is approximately five, say, maybe four or five. So the area changes from -- from 100 percent down to about 25 percent according to these results on average. But then later on, they make a comment that the collapsibility index is about .5, so there's something I don't quite

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understand in terms of relationship between those two results. But either of those results can be used to come up with the sort of information that you're asking about.
Q Did their -- did their results on neutral breathing, were those consistent or different from what Murphy found?
A I have to look at both papers to --
Q Okay.
A -- try and answer that question.
So the Murphy paper says that during normal breathing, the area changed from 249 millimeters squared on average to 310 millimeters squared on average. The numbers in the Laborda paper are significantly higher. They find areas of 400 meters squared, 380 meters squared, 342 meters squared. So the areas, although they're not completely different, there's a difference in terms of the average areas which were observed.
Q So which -- which is larger?
A The -- I need to look at this carefully.
If I'm looking at the correct numbers, the numbers for the areas in the Laborda, et al., paper are larger.
Q And that paper was not available to

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medicine or science until -- looks like it's published October 2014, true?
A That's correct.
Q Now, with respect to Valsalva movements, I take it that you do not have any information about how often any person with a Bard filter has a Valsalva event?
A No, I don't have any information on that.
MR. O'CONNOR: Belated objection to the form.
BY MS. DALY:
Q So at page 11, the last paragraph on that page where you're talking about that Laborda paper that we just discussed, which is Exhibit 13, you say your calculation showed that a filter arm experiencing those strains would last only about 500 Valsalva maneuvers before fracturing, correct?
A Which line is that on?
Q Let me see where --
A I see it. Yes, I see it. Yes, I agree.
Q Okay. So do you know if there's a range amongst people who do have Valsalva movements of what the change in diameter would be?
A Well, the information in the Laborda, et al. paper indicates that that's the case because

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there are ranges for the areas before Valsalva and there are ranges for the areas during Valsalva, so, therefore, it suggests that there's a range of area changes which occur because of Valsalva.
Q So person to person there are differences?
A Yes.
Q You would agree?
A Yes.
Q Similarly, person to person there are differences in what changes would happen in their anatomy in normal respiration; would you agree with that?
A I would agree with that.
MR. O'CONNOR: Form.
BY MS. DALY:
Q Okay.
A Again, from the Murphy, et al. paper, that's the suggestion.
Q Okay.
A Or that's the indication, I should say, yeah.
Q And of course the numbers of times people have Valsalva movements during the time they have a Bard filter in situ would range greatly?
A I agree.

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MR. O'CONNOR: Form.
BY MS. DALY:
Q Okay. Have you seen any case that you --
A Can I revise that answer?
Q Yes.
A Although I agree from the position of a non-expert in what causes people to do Valsalva, knowing what is involved in terms of what causes Valsalva I can understand that there would be a range of -- of numbers of times that an individual would undergo such a maneuver.
Q And, for example, if you had a respiratory problem and you were a chronic person that had to do huge coughs, for example --
A Yes. Yes.
Q -- that's a Valsalva type, correct?
A Yes, that's right.
Q Okay. Do you know of any case that you have looked at as an individual case in this litigation where a doctor has reported that a patient had frequent Valsalva es- -- episodes between the time of implant and the time of fracture of the filter?
A I didn't see any such information in the medical records that I studied, and I didn't see

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any such comment in the experts' reports that I read, although I don't know if that can be ruled out. But, yeah.
Q Did you -- do you -- did you see anything in the literature that indicated that changes due to respiration, normal respiration, or Valsalva put strains on an IVC filter that resulted in tilt, migration or perforation?
A Well, there's a bench test study that Bard carried out in which they compared the Meridian filter with some other filters, and they imposed what would be representative of Valsalva changes of shape to a synthetic vena cava and they found that that caused tilt of the -- of the filters involved. So I think that's the only study I know where anything like what you asked me about is -- is looked at.
Q And do you know what --
A Sorry, I should say the only one I'm aware of.
Q Do you know which filters in that test performed any tilt in a Valsalva condition?
A I'd have to look at my report or --
MR. O'CONNOR: Well, look at it.
THE WITNESS: -- look at the original

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report to -- to -- to figure that out.
BY MS. DALY:
Q Yeah, I wasn't sure whether you meant it was with respect to the Meridian or something they were comparing it to.
A Well, they were doing comparisons, but my point of my answer was simply that they observed the Valsalva maneuver -- sorry, the Valsalva simulation in the experiment would cause the Meridian to tilt and some other filters to tilt.
Q Was it one Valsalva event?
A No, it was multiple Valsalvas.
Q Okay. And that test will tell us how often that was?
A Yes.
Q How many times it was --
A Yes.
Q -- and what the pressures were, and so on?
A Right. Correct.
Q Okay. What about any either Bard testing or any literature that tells us whether changes during normal respiratory behavior or Valsalva caused perforation?
A I know of no such study. I'm not aware of it.

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Q Or any Bard information?
A Or any Bard...
Q All right. Let's look a minute at page 9, paragraph 2 and 3. And we're talking about the arms at the sheath and strains on the arms relative to the sheath.
A Right.
Q Okay. All right. One of your -- one of your findings there is that "A strain concentration where the arm enters the sheath can elevate the alternating strain in some cases by factors of 10 or more."
Do you see that?
A I see that, yes.
Q What analysis did you perform to evaluate that?
A We carried out a finite element -- I carried out -- well, it was with Professor Begley, I carried out a finite element simulation of an arm touching the edge of the sheath where it -- where the arm entered the sheath, and the chamfer on the cap we chose to be, as I recall, 5 microns and found that there were strain concentrations higher than 10.
Q That was your 2D FE?

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A That was the 2D FE --
Q Okay.
A -- finite element analysis.
Q Did you present any calculations that demonstrate that the strain near the sheath would increase by that factor?
A Sorry, could you repeat that question.
Q Yeah. Did you -- did you present any actual calculations that demonstrated that the strain near the sheath would increase by a factor of 10 plus?
A I believe that we presented color contour plots of the strains, and I'd have to review that to see exactly what information is in it.
MR. O'CONNOR: Are they here?
THE WITNESS: They're here, yeah.
BY MS. DALY:
Q Yeah, and my next question was: Were those results presenting stress or strain? So...
A Oh, I see.
These are stress plots.
Q Okay. And did you use -- for that 2D FEA analyzing the sheath interaction, did you use a linear elastic material response?
A Yes.

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Q Okay. At the increased strain levels that you're describing, this 10 -- 10 times greater, is the assumption of linear elastic material response valid?
A Well, the -- it depends on what the imposed level of -- of strain is, so if you take the nominal strain and multiply it by the strain concentration factor and that is below the limit to linear elastic behavior, then the result is a correct estimate of the strain concentrating effect of the -- of the feature.
If the nominal strain is higher and drives the strain at the -- in the strain concentration to higher than the limit on linear elastic strain, then the calculation is not exactly correct. However, strain, because of its nature, since it's a geometric effect, the level of strain that you're going to get when the material becomes nonlinear is not going to be very different from the level of strain that you get when the -- when the -- in terms of the strain concentration factor is not going to be very different from what you predict using a purely linear analysis.
Q But for the purpose of the work that you did with these stress values, is it correct that

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the stress values you determined in your analysis rely on your assumption of a linear elastic response?
A Well, the -- the -- the strain levels in the region where the strain has exceeded the limit on linear elastic strain would be affected by the fact that there is nonlinear behavior beginning to set in. However, around the region where you have nonlinear behavior, there is a zone in which the response is still linear because the strains are low enough that the strains remain in the lineal elastic regime, and those strains control the way that the behavior occurs closer in to the -- to the place where there is a high strain and constrain that motion and, as a result, the strain that you get at the strain concentration in the nonlinear material is relatively -- is little different from what you get from the linear elastic analysis.
And this is something that I've studied in my own research. It's -- it's a known consequence of compatibility that is associated with the way materials deform.
Q And you did not then take this analysis to the point of a bench test to see if you could actually measure strains of 10 times greater or

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whatever?
A No --
MR. O'CONNOR: Form.
THE WITNESS: -- I have not done such a bench test.
BY MS. DALY:
Q Okay. Now, we've talked about the chamfer issues in these cases --
A Yes.
Q -- several times before.
A Yes.
Q Okay. Is it your opinion that any of the fractures of Bard filters where we've been able to see the filters, or Richie and Fasching have seen the filters, have occurred from struts actually coming in contact with a chamfer?
A Well, some of them appear to have been generated that way because the fracture surface is very close to being adjacent to the -- to the chamfer and --
Q And the information that you would have about that would be based on the SEM work that either Dr. Fasching did or Dr. Richie, true?
A That's correct.
Q All right. Are you aware of any example

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of a fracture in a strut where there's evidence of it coming in contact with the chamfer in a G2X, Eclipse, Meridian or Denali?
A Sorry, could you repeat the question.
Q Yes.
Are you aware of any Bard filter having a strut fracture where there is evidence that that strut came in touch -- came in contact with the chamfer in any G2X, Eclipse, Meridian or Denali?
MR. O'CONNOR: Form.
THE WITNESS: I would need to review Dr. Fasching's report and Dr. Richie's report to see whether that's the case.
BY MS. DALY:
Q Well, I will tell you that they have not looked at explanted Eclipse, Meridian or Denalis, and they've had a couple of G2Xs.
A So did you ask me about G2Xs?
Q Yeah.
A Well, then I'd have to review those reports to see whether the G2X has that feature.
Q Would you rely on what Dr. Richie or Dr. Fasching found about whether there is an example or not an example of a filter with evidence of fracture -- a G2X filter with evidence of

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fracture of a strut contacting the chamfer?
A I would rely on them both where they're consistent with each other, and then I'd have to make a judgment if they came to different conclusions.
Q All right. Very good.
Are you -- same question about are you aware of examples of filter fracture caused by wire-to-wire fretting or contact independently of whatever Dr. Fasching and Dr. Richie have found?
A I --
MR. O'CONNOR: Form.
THE WITNESS: I don't have any independent information on that.
BY MS. DALY:
Q Okay. And if they do not have any examples of evidence of fracture from fretting wire to wire of any filters from G2X on to Denali, do you have anything more that you could give me for evidence that that can occur in those filters?
A No.
MR. O'CONNOR: Form.
THE WITNESS: I have nothing addition- -- additional.
BY MS. DALY:

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Q Okay. The other thing that you and I talked about before, and Dr. Richie also comments on, is strain concentrations in an area in the arm struts, as opposed to legs, sort of up towards the cap, correct?
A Yes.
Q All right. Do you agree with Dr. Richie that even if you see an explanted filter, you cannot necessarily determine -- let me start over. Let me start over.
In a filter that has not been retrieved, are you aware of any way to determine the precise point at which that filter fractured?
A No.
MR. O'CONNOR: Form.
THE WITNESS: I'm not aware of any safe method that -- that would be feasible.
BY MS. DALY:
Q Okay. And what about being able to look at the surface areas of two sides of fractures, what's left with the filter and the -- and the strut, in situ, you would agree that you can't do that safely?
A You can't do it safely if both pieces are still in the patient.

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Q And would you also agree that if you do not have retrieved filters and/or the fractured strut, that again you cannot do an analysis to determine what type of fracture it is?
MR. O'CONNOR: Form.
THE WITNESS: I would say --
MR. O'CONNOR: Foundation.
THE WITNESS: -- if you have one -- if you either have a detached piece or if you have the filter itself, you can do an analysis of the fracture surface that you do have.
BY MS. DALY:
Q If you have neither?
A If you have neither, you -- you can't do it safely.
Q Okay.
A Or if it's -- or if the filter has disappeared, you can't do it.
Q Right. All right.
Are you aware of cases that you have looked at in this litigation where there has been perforation or tilt in the absence of fracture?
A You mean one of the five cases that we're --
Q No, I'm talking about --

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A In general.
Q -- in your whole experience with different cases.
A Can you repeat the question, please.
Q Yeah.
Have you done any work -- given a report on any cases in this litigation where the complications were tilt and perforation only without fracture?
A "This litigation" meaning any --
Q Bard filter cases.
A -- case -- yeah, I -- I recall that there are some cases like that.
Q Do you recall there being some cases you've worked on where there was a fracture and no tilt?
A I don't recall whether that's the case, but I'm not sure.
Q How about fracture and no perforation?
A Again I'm not sure. Yes, I'm not sure.
Q On page 12 of your report, paragraph 4.
A Sorry, which page?
Q Page 12. Counting full paragraphs, I'm looking at paragraph 4, and if you go down to line 5 it starts with "For example."

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A Yes.
Q "The possibility of strain concentration should have been eliminated either by breaking, curving or chamfering the edge in question at the mouth of the" -- "of the sheath."
We've talked earlier this morning about chamfer changes and the breaking or doing the beading, or whatever, to change that, correct?
A Yes.
Q All right. Do you think that there is a method by which Bard can eliminate strain concentrations completely with respect to the chamfer?
A Well, there's two ways. One is that you isolate the arms completely from the cap by holding the arms in some way so that they can't move close enough to the cap to contact it, and then you have to be very careful about how you design -- how the arm goes into whatever's holding it because you have to avoid strain concentrations there as well.
And then you could do something such as was done for the Denali, which is that you would make it from a tube so that the contact between what you would otherwise call a cap is -- is not a feature of what can happen. Although I should

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comment that even those situations generate strain concentrations, but it may be very small.
So I suppose the simplest answer to your question is that you can't reduce strain concentrations to one in any sort of feature that has a complicated shape.
Q You cannot eliminate that prob- -- that problem?
A Yes, you can't eliminate strain concentrations other than in the simplest --
Q Okay.
A -- of shapes.
Q And you haven't tried to put together a prototype chamfer that would do that --
A No. No.
Q -- that is, eliminate strains?
A No.
Q Okay. Foot fractures, let's talk about that for a minute. Dr. Richie recently testified that he saw fewer foot fractures in the G2 filter. Do you know if that's correct or not?
A I don't know independently whether that's correct or not.
Q Do you know if there was any modification to the G2 that -- from your engineering -- from an

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engineering standpoint may have reduced fracture to the feet?
A You mean from the Recovery to the G2?
Q Yes, sir.
A The ankle was thickened, and that would have reduced the nominal strains that were present in the material and then what would fall from that is the question of whether any gouge or other kind of feature that would concentrate strains would still elevate the strains to dangerous levels.
Q Do you know how many foot fractures have been reported with any of Bard's filters from the G2 onto the Denali?
A I haven't studied that.
Q Okay. Do you have the opinion that a foot fracture causes tilt, migration, perforation or fracture?
A I have the opinion that a foot fracture would lead to tilt, and since it's my assessment that tilt leads to perforation I think that would then be a second consequence. And since it's my opinion that a perforation can lead to fracture, I think that that would be a follow-on consequence of -- of a foot fracture.
Q What if the -- what if the leg is

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perforating to the point that you've discussed before, that is the filter's now all the way out to its former -- or greatest extent that it could be out, would you expect a foot fracture to contribute to tilt or migration?
A Well --
MR. O'CONNOR: Form. Foundation.
THE WITNESS: My assessment is the foot fracture would have taken place while the foot was still engaged with the vena cava wall, and, therefore, when it was broken it would have had an impact on the stability of the filter. But once perforation has taken place and any tilt that's associated with that, then the implications would be less direct and probably not involved at all.
BY MS. DALY:
Q So do you know if when a foot fractures if the leg on which it was, that leg starts moving freely within the vena cava? Do you know that?
A You mean does it move by large amounts?
Q Or does it move at all?
MR. O'CONNOR: Form.
THE WITNESS: I -- I don't know for any certainty that that's the case.
BY MS. DALY:

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Q And for -- for there to be additional strains on a leg that is missing a foot, would there need to be some movement in the leg?
A Could you repeat the question.
Q Yeah.
If you've got a leg that's now missing a foot, is it your opinion that the leg has to be moving in some way to have sufficient strain put on it that it would later fracture?
MR. O'CONNOR: Form.
THE WITNESS: You mean would the vena cava wall have to move the leg in some way? It's my -- my --
BY MS. DALY:
Q Or the blood flow maybe. I don't know.
A Say that again.
Q Or blood flow.
A Well, whatever -- whatever would cause the deformation, there would have to be some sort of distortion that would take place for a fatigue fracture to follow because fatigue fracture is generated by strain, strain changes.
Q Have you identified any case that you've worked on thus far that had a foot fracture that you believe led to a later leg fracture?

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A I haven't --
MR. O'CONNOR: Form.
THE WITNESS: -- studied that.
BY MS. DALY:
Q In what percentage of foot fractures does migration of the filter occur?
A I don't know.
MR. O'CONNOR: Form.
BY MS. DALY:
Q When Bard electropolished the Eclipse filter, did that have any impact on improving the resistance to foot fracture?
MR. O'CONNOR: Form.
THE WITNESS: I don't know for -- for sure, but in principle it would have improved the resistance to foot fracture.
BY MS. DALY:
Q And how so?
A Because it smooths the surface and makes the initiation of fatigue cracks somewhat less likely.
Q And again, you don't know about the numbers of events of foot fractures reported in Eclipse, for example?
A No. No.

Q Okay. What causes -- what causes failure of legs in Bard filters?
A Well, one possibility is the blood clots repeatedly impact the filter, and even a single blood clot, as the blood flows up and down -- not down, but as the pulsatile flow of the blood moves the clot around, that would push the clot against the leg multiple times and so that could cause -- that would cause strain -- strain increments to the -- to the material in the leg that could ultimately cause it to fracture by fatigue.
There's another possibility, which is that if the arms and the legs are endothelialized to the wall of the vena cava and the vena cava is stiff enough to resist axial motion of the points where the arms and the legs are glued to the wall of the vena cava, it can cause some additional strains on the legs, and on the arms for that matter, because of the constraint that makes it more difficult for the filter to respond to the expansion and contraction of -- of the vena cava. So that's another possibility for where leg fractures can come from.
Q So the first one that you talked about is your water hammer --

A That's right.
Q -- theory.
A Well, it's not my water hammer theory -- well, first of all, it's not my theory. But secondly, it's not only my water hammer model but it is -- it is a consequence of the actions of the clots on the filter which in one interpretation can be looked at in terms of water hammer.
Q Okay. We're going to talk about that in a separate thing in a moment.
So the second thing you're talking about that could lead to leg fracture is you've got perforating legs; am I getting this right?
A Perforated or unperforated, but they're endothelialized to the wall of the vena cava.
Q So they're not moving?
A They're moving because the vena cava is expanding and contracting, but otherwise their relative motion is constrained.
Q And, in addition, the vena cava is stiff enough that on those constrained legs, let's talk about legs for a minute, that there's a possibility that could cause fracture?
A Yeah.
Q Do I have that right?

A Right. And the stiffness --
MR. O'CONNOR: Form.
THE WITNESS: -- we're now talking about is -- is more or less the axial stiffness of the vena cava, not the stiffness in the circumferential direction.
BY MS. DALY:
Q And stiffness of a vena cava could be a range of stiffness being patient-dependent, true?
A Yes.
MR. O'CONNOR: Form.
BY MS. DALY:
Q And it could also be impacted by organs?
A Yes.
Q And the stiffness of those organs contributing to vena cava stiffness could be patient-specific?
A Yes.
Q Okay.
A Can I add one amplification of my answer, which is that let's say that an arm and a leg -- an arm and a leg are perforated and they get inserted into, say, the vertebrae and they get firmly connected to the vertebrae and now the vena cava's expanding and contracting, that could be a very

severe stiffness constraint on whether the relative motion of the arms and the legs can be accommodated as the filter, if you like, tries to stretch. So that -- that's a possibility.
Q Do you have any case that you can point to that you have worked on where there was imaging evidence of perforation, tilt or migration that occurred before a leg fracture?
A I haven't looked into that.
MR. O'CONNOR: Belated objection to the form of the question.
BY MS. DALY:
Q Have you done any work to determine what modifications Bard could have made to the legs themselves to improve on those legs' contribution, if any, to tilt, perforation, fracture or migration?
A No, I haven't looked into that.
Q We've talked a little bit about the anchors and limiters present on the Meridian. Is it your opinion that those are reasonable modifications by Bard to -- to improve resistance to migration, tilt and perforation?
A It's a reasonable concept for how the tilt and migration behavior can become -- can be

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limited.
Q Would -- do you have an opinion whether those anchors or limiters on the Meridian would add fracture resistance to that filter?
A I have no opinion on that.
Q Same questions with Denali, do you think that the limiters that the Denali has will act to improve resistance to migration, tilt, perforation and fracture?
MR. O'CONNOR: Form.
THE WITNESS: It's -- it is reasonable to expect that there will be some effect on -- on tilt and migration and that those would have possible knock-on consequences to perforation and fracture. And so I'd like to revise my answer about the Meridian in the same way, that the caudal anchors, to the extent they limit tilt and migration, they could have beneficial effects on perforation and fracture.
BY MS. DALY:
Q Okay. What modifications to the G2 filter assisted in resistance to cephalic migration? Do you have an opinion on that?
MR. O'CONNOR: Form.
THE WITNESS: I'm not aware of any changes

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that would have had an impact on cephalic migration.
BY MS. DALY:
Q Are you aware that the incidents of cephalic migration of G2 and later Bard filters has -- has improved greatly?
A I'm not aware of that.
Q What about the change to the G2 filter contributed to caudal migration, if you have an opinion?
MR. O'CONNOR: Form.
THE WITNESS: Sorry, can you repeat the question.
BY MS. DALY:
Q Yeah.
Do you have an opinion about whether any design modification that Bard made to the G2 filter resulted in caudal migration?
A You mean going from the Recovery to the G2 filter --
Q Yeah.
A -- whether that improved caudal migration?
Q No, whether it caused it.
A Whether it contributed to it.
Q Yes.

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A I have no opinion on that because I have not studied it.
Q Okay. Have you studied what the mechanism is anatomically to create caudal migration in any Bard filter?
A I've not studied that independently.
Q Okay.
A I've only --
Q What does that mean?
A What does it mean. I've looked at the Bard report of their bench test --
Q Okay.
A -- and -- which is suggestive of a mechanism that can drive caudal migration.
Q Okay.
A Because it's -- because it's associated with tilt.
Q Okay. And have you done any work to determine how Bard might have modified its filters to reduce tilt that you associate with caudal migration, with contributing to caudal migration?
MR. O'CONNOR: Form.
THE WITNESS: Well, the only observation I have is that the effective caudal anchors would have had a beneficial effect, but otherwise I've

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done no thinking or studying of that.
BY MS. DALY:
Q All right. If you look at your report, page 13, it's the G2 Express filter.
A Yes.
Q We've talked about the cap change I think exhaustively.
A Yes.
Q And did you have any other observation of the G2 Express as -- as having characteristics that that particular filter had that contributed to any of these complications different from Recovery and G2?
A Well, the cap -- sorry, the hook on the cap, because it would have touched -- during tilt it would have been touched, under certain assumptions about how the filth occurs, it would have touched the wall of the vena cava first as opposed to other points on the cap, and that would have had some effect on what happens in terms of perforation and tilting of the -- of the filter.
And it's my assumption that the big hook would have taken -- would have been -- would have taken longer to perforate through the wall of the vena cava than the cap itself, although that's just

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an assumption, it's not a -- it's not anything definitive.
Q And if the hook took longer to perforate, how would that impact any of these complication events?
A Well, to the extent the tilt contributes to fracture, it would have helped to reduce the tendency for fracture to occur.
Q Okay.
A But I don't think that would have been a big effect, but that -- that's a possibility.
Q Do you understand from your reading or looking at any design drawings that the inclusion of the hook on the G2X was at the recommendation of user doctors who felt it was a -- an improvement to methods for retrieval?
MR. O'CONNOR: Form and foundation.
THE WITNESS: I've seen comments in various documents that say it has improved retrievability.
BY MS. DALY:
Q You don't hold an opinion on it?
A I have no opinion on it.
Q We've talked about the Eclipse and electropolishing. And if you look at page 15 of

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your report, full paragraph 1.
MR. O'CONNOR: What page?
MS. DALY: 15.
Q In the first about five or six lines you're talking about that change, and then you say "I would expect a marginal improvement in terms of incidents of fatigue fractures in the Eclipse model."
A Yes.
Q And what do you mean by "a marginal improvement"?
A Well, I mean a small improvement. I'm not -- I -- I don't want to specify a specific number, but there would have been a small number of filters that would not have failed because of the electropolishing. So I'm not being very clear on this.
So if you take a certain number of filters that are going to fail without electropolishing, the number of filters that would fail with electropolishing would not be that much different as -- yeah, not much -- not that much different.
Q Okay. And with respect to filters that fail due to surface -- non-electropolish surface conditions, do you have any opinion about the

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degree to which that issue contributed to any fractures in Recovery or G2?
A No, I have no opinion about that.
Q Okay. Would you leave that to Dr. Richie to discuss?
A Yes, I would.
Q All right.
A Although can I make one further comment?
Q Of course.
A That she gave me a shape of a gouge, I could then estimate the strain concentration, but other than that I would not look at that question.
Q Do you know whether surface conditions were of particular great moment to contribution for fractures in G2s or Recoveries?
A I don't know --
MR. O'CONNOR: Form.
THE WITNESS: -- I just leave that to Dr. Richie.
BY MS. DALY:
Q Okay. Did the electropolishing of the Eclipse have any other positive impact on resistance to any other complication? We've talked about feet, but what about electropolishing contributing to resistance to perforation,

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migration or tilt?
A Other than reducing the number of fractures to whatever extent that occurs, I don't -- I can't think of any consequence that the electropolishing would have had. It might have had some consequence to epithelialization, but other than that I don't see any direct consequence.
Q Okay. And I guess what you're saying, too, is if -- if your hypothesis is correct that fracture equals tilt or other things, if it didn't fracture because electropolishing kept it from fracturing, it would also help it not tilt or perforate?
A Yeah, I'm -- yes. For example --
MR. O'CONNOR: Form.
THE WITNESS: -- if a fracture was -- would have otherwise contributed to tilt and perforation, then that consequence would have been eliminated to some extent.
BY MS. DALY:
Q Okay. Meridian, you talk about that at page 16 of your report at the bottom. And you note that the Meridian has three anchors added to the arms at the wrists and three anchors added at the arms at the elbows, correct?

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A I -- yes, that's correct.
Q And do you know what the purpose of those two different placements of anchors was?
A I don't know definitively, but I've -- I've made a -- I feel like a guess as to why that was done.
Q And what do you think was the reason?
A I think it was -- let me -- let me look at what I say. Yeah, it would deal with vena cava diameters of different size with, and I'm making the guess, that the ones at the wrist will help to inhibit caudal migration and larger-diameter vena cavas and the ones at the elbow will help to inhibit caudal migration in smaller-diameter vessels.
Q All right. If you look at page 17, it's first and second full paragraphs, you're talking about Meridian bench testing.
A Yes.
Q Okay. And you talk about -- you say Bard used a more aggressive protocol for certain tests on Meridian that it did not use I guess on earlier filters? Is that what your point is.
A That's my point, yeah, that -- yes.
Q But then you're still critical of the

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Meridian testing. Can you explain that to me?
A Well, the Meridian testing was not done in what would be identifiable as worst-case conditions, so perforation was not accounted for in the fatigue tests. There may -- well, I don't recall whether tilt was allowed for in the fatigue tests, but combinations of -- of tilt and perforation were not allowed for, so aspects like that were deficiencies in the approach to the testing.
Q So your criticism is that you don't believe they did it to worst case?
A That's correct.
Q All right.
A And -- but in addition, they didn't design the test to identify failure conditions, and, therefore, they -- they did not have a basis on which to determine whether the test was realistic in truly assessing the failure and the mechanisms of failure which were possibly present in the filter.
Q So you're critical, for example, that the testing didn't simulate perforation? Is that what you're saying, by way of an example?
A Yeah, that's one example of what I'm

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talking about.
Q Okay. What's another example?
A That it didn't account for combinations of tilt and perforation. It didn't account for the effect of endothelialization.
Q Okay. Do you know if any other IVC filter manufacturer tests with those combined types of issues?
A I'm not allowed to comment.
Q Okay. So you're not going to rely on what some other company is doing to say Bard could have done this?
A No.
Q And you have not developed test protocols to try out, to see if one can successfully test for perforation with a tilt and what happens for strains or any other combination?
MR. O'CONNOR: Form.
BY MS. DALY:
Q True?
A That's correct.
Q On page 19, paragraph 2, it's -- I wanted to ask you about five lines from the bottom -- six, actually. You're talking about "I note that no changes were made to the Meridian design that would

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improve cephalic migration resistance."
Do you see that?
A Yes, I see that.
Q Is that because your understanding is those anchors will only prevent caudal migration?
A Yes, that's right.
Q Okay. Have you seen any tests about Meridians having -- being tested for cephalic migration?
A I don't recall seeing any tests like that.
Q Do you know of any incidents reported where Meridian filter has migrated cephalically?
A I -- I don't recall.
Q And you of course have not tested the Meridian in any way?
A No, not at all.
Q Let's look at your supplemental report of April 17 (sic), '17. It's Exhibit 3, page 2.
A Exhibit 3? Thank you.
Q Yes.
A Which page?
Q On page 2 of your report.
A Okay.
Q And I think I wanted to ask you --
MR. O'CONNOR: Hold on one second. Let me

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find it.
Go ahead and start. I'll find it.
BY MS. DALY:
Q You're -- you're talking about an FEA by Harrison at the top of that page.
A Yes.
Q To obtain conservative results for the magnitudes of alternating strains.
What is your criticism there on that testing relative -- I mean that FEA relative to the Meridian? The same things we're talking about with respect to the testing that we just talked about or something different?
A Okay. So when I say he's imposed a rigid constraint, this is the question of rotation of the arm relative to the wall of the vena cava as the expansion and contraction of the vena cava takes place, which would effectively double the level of strain generated by that motion.
Q And you have not done an FEA to see if in fact that would double the strains as well, right?
MR. O'CONNOR: Object to the form.
THE WITNESS: Well, I've not done a finite element analysis, but that's not necessary to do because the Euler-Bernoulli bead analysis provides

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you with that result.
BY MS. DALY:
Q And then you have, of course, not done any bench testing on the Meridian to see how it would really hold up in actual testing?
A No, I've done no bench testing.
MR. O'CONNOR: Belated objection to the form of the question.
BY MS. DALY:
Q So to that point, you're -- you're making -- you're just critical that the same erroneous, according to you erroneous, variables were used?
A Assumptions.
Q Assumptions --
A Yes.
Q -- were used?
A Correct.
Q But we've already talked about those?
A Yes, we have.
Q Yes.
A But I note further down the paragraph, there's other comments, which is that the Harrison calculation took no account of perforation endothelialization of the filter arm to the wall of

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the vena cava, not of tilt.
Q And we talked about that?
A We talked about that.
Q Okay. So going back to your main report again, I'm on page 18, paragraph 2, that first line you say that "In one of the caudal migration tests, the bar was set very low by Bard as to what was required of Meridian."
What do you mean by that?
A Can you tell me which paragraph we're in?
Q Yeah. It's the second full paragraph, the first sentence, on page 18.
A Well, I mean that it -- the -- the test was simply to compare the caudal migration of the Meridian with the caudal migration behavior of the Eclipse.
Q Okay.
A And since the caudal anchors would have an effect on the tendency for caudal migration to take place in the Meridian, it was almost certain that the Meridian would have better performance than the Eclipse.
Q Sure. So why was that setting the bar low? I guess I'm not following you.
A Well, it was simply comparison between a

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filter that should have had better performance with one that -- that -- that did not have that level of performance, as opposed to a test in which there was an objective criterion for what -- for what was adequate resistance to caudal migration.
Q Okay. So you don't know what those values are, in other words, you don't know what the Meridian's caudal migration resistance is by load or anything, right?
A Well, other than the results from that bench test, no.
Q Okay.
A I don't know.
Q And you haven't tried to do that yourself?
A No, I have not.
Q So it may be fantastic?
MR. O'CONNOR: Form and foundation.
THE WITNESS: I won't comment.
BY MS. DALY:
Q You just don't know?
A I don't know.
Q All right. In your -- back to your 4-7-17, Exhibit 3 report, still on Meridian but on page 6, you cite to two papers, Nissan/Romano and Wu, W-u.

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A Correct.
Q In the Nissan/Romano paper, they detected two arm fractures in a single Meridian, correct?
A That's correct.
Q And then in the Wu paper, they detected an arm fracture one year after implant in the Meridian; is that right?
A That's correct.
Q And you note that there has been no examination, apparently, of either the filter from which the fracture happened or the fractured piece in either of those Meridians to tell us what type of fracture that was; is that fair?
A Yeah, I --
MR. O'CONNOR: Form.
THE WITNESS: -- don't know examination.
BY MS. DALY:
Q Okay. And you quote to those events for what purpose?
A Just to identify the fact that -- that Meridian filters can fracture in vivo.
Q Does -- does two reports of Meridian, or even more than two reports, support that it's prone to fracture?
A I think it does with the definition that

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"prone" means it can happen.
Q Okay. So that's your definition, it can happen?
A Yes.
Q "Prone" means can happen, not is likely to happen?
MR. O'CONNOR: Form.
THE WITNESS: It -- I -- I would just repeat my definition, that prone to fracture means it can happen.
BY MS. DALY:
Q Can happen. Is it more likely than not to happen in a Meridian?
A I don't know whether that's the case.
Q Have you ever used the term prone to fracture, tilt, perforate or migrate relative to a Bard filter where your def- -- where your definition was something other than can happen?
A I don't believe so.
Q All right. On to Denali, and back, I'm sorry, to your March report, Exhibit 2, page 20. On page 20 you give sort of an overview of the changes to the Denali filter?
A Yes.
Q Okay. And it's -- there are a lot of

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differences in the -- from the previous iterations, true?
A Yes.
Q All right. And you are still highly critical of the Denali filter why?
A Because it -- it wasn't changed -- well, although there's lots of differences, it wasn't changed that much from the basic shape of the Meridian filter, and, therefore, its basic behavior in the same circumstances as the Meridian filter would have been quite similar.
Q It has a different cap?
A Yes.
Q It does not have the -- the chamfer contact possibility that previous ones did, true?
A I agree that there are some changes that eliminate some aspects of the expected behavior, but what I'm saying is that many of the -- of the features of the behavior would have been left unchanged because of the basic similarity in shape of the Denali filter to the Meridian filter.
Q To what extent can the Denali perforate?
A I -- you mean what is the rate of perforation?
Q Yeah.

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A I don't have any information on that.
Q What about its ability to migrate either cephalad or caudal, do you have any information on that?
A I have no direct information on that.
Q So your criticism is that there are aspects of the Denali that in your opinion will allow it -- make it that it can tilt, perforate, fracture or migrate?
A Yes. And I -- I -- I should comment that there is some description of -- of events for the Denali in the supplementary report.
Q Right. Right. And I'm going to --
A I don't mean to ignore --
Q -- get to those.
A -- that.
Q Yeah, I'm going to get to those.
Okay. Do you know of modifications to the Bard filters, any of them, that would have made them unable to fracture, tilt, perforate or migrate?
MR. O'CONNOR: Object to the form of the question.
May I hear the question back again.
THE WITNESS: Could you repeat the

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question.
MS. DALY: Can you read that one.
(Record read as follows:
"Do you know of modifications to the Bard filters, any of them, that would have made them unable to fracture, tilt, perforate or migrate?")
THE WITNESS: I haven't studied that.
BY MS. DALY:
Q So you -- you do not have an opinion that there was a method by which Bard could eliminate tilt, fracture, perforation or migration in any one of its iterations from Recovery to Denali?
MR. O'CONNOR: Form and foundation.
THE WITNESS: You mean simultaneously eliminate all of those negatives?
MR. O'CONNOR: Form.
BY MS. DALY:
Q Or one by -- or any of them, either all of them or, yes, you could -- you could have eliminated completely this, this or this.
A Well, I -- I think it's possible to eliminate one of the phenomena by itself but --
Q What's that?

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A Possibly perforation.
Q And how would you do that?
A Make a big penetration limiter.
Q Okay. And you had not done a prototype of that, correct?
A No, I have not.
Q You have not determined what other unintended consequences it might have to the design or benefits of the filter?
A No, I haven't studied that.
Q All right. With respect to Denali, we talked earlier today about Dr. Stavropoulous's study, the final -- he did the clinical trial?
A Yes. Correct.
Q Okay. And if you would look at that again. I forget what we've numbered that.
A Oh, do I still have it? Yes, I do.
Q Is it there?
A Yes. No. 12.
Q Okay. 12. If you look at Table 4 on page 7 of that. Just count in 7, I'm not sure it's actually 7. Table 4.
A Yes.
Q Okay. That study --
A Sorry, Table 4.

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Q Yeah.
A I'm still at Table 2.
Q Okay.
A Table 4.
Q Okay. The data from that study showed zero fractures in the Denali?
A I -- yes.
Q Zero migrations?
A Yes. Zero migrations greater than 2 centimeters.
Q Yes. Zero tilts greater than 15 degrees or --
A Yes, zero tilt greater than 15 degrees.
Q Three penetrations at implant?
A Yes.
Q And two penetrations at retrieval?
A Well, 3 out of 200 at placement, 2 out of 121 at retrieval.
Q Okay. I read that right?
A Yes.
Q Yes. Okay.
Then in your Denali-specific report, which is the April report, back to Exhibit 3 --
A Okay.
Q -- page 7 at Section 2.2. Yeah, top of

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the page, 2.2.
A Yes.
Q You report on a case report by Dr. Kuo of a Denali fracture, correct?
A In the Kuo and Robertson paper. Is that what you're --
Q Yes.
A Yes.
Q And then there's a paper by Sathyanarayana -- I will spell that later -- of one Denali fracture, correct?
A Can you remind me how far down that one is.
Q Yeah, he's --
A We're on page 7?
Q Yeah. Where is Sathyanar- --
MR. O'CONNOR: What report are we looking at again?
MS. DALY: The April one.
THE WITNESS: Supplementary report, April 7.
BY MS. DALY:
Q He is citation 12.
A Oh, it's almost -- it's two-thirds of the way down the paragraph.

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Q Oh, I see it.
A Yeah.
Q Yep.
A Yes.
Q Okay. So you cited to that page -- that paper that detected an arm fracture in a Denali 13 months after implant?
A Correct.
Q And then you cited to Majdalanay on two other Denali fractures?
A Correct.
Q And he was reporting on some fractures that he had found in the raw database?
A That's correct.
Q First of all, you don't know whether the paper that he's counting the stuff from Majdalanay, whether that included the previous reports of Denali fracture from Kuo and Sathyanarayana?
A No, I don't know.
Q Okay. Now, the Kuo and Sathyanarayana reports do not state whether the filter was tilted, perforated or migrated before fracture, do they?
A I don't exactly recall, but I didn't write it down so I -- I'm assuming that that's the case.
Q Okay.

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A I would have written it down if I observed that in the papers.
Q And the Majdalanay reported that both patients he saw with a filter -- a Denali fracture had center filters and there was no comment about perforation or migration. Let me show you that.
We'll mark that as -- and I'm happy to show you the other ones, too, if you'd like. This is 16, Majdalanay.
(Whereupon, Deposition Exhibit 16 was marked for identification by the Court Reporter.)
THE WITNESS: You've given me two copies of something.
BY MS. DALY:
Q Okay. Give me that back.
Am I right, that --
A Oh.
Q -- he reports that they were centered?
A Well, the wording I find -- the centering wording may be elsewhere, but it's -- the wording I found, this is the Madja- -- Majdalanay paper --
Q Uh-huh.
A -- it says "No filter tilt or angulation of the IVC was present relative to the Denali IVC

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filter at implantation." I don't know if it's a comment about it later on as well.
Q Yeah --
A And --
Q -- I didn't see anything about him noticing --
A Yeah.
Q -- any other complication in connection with that fracture.
A Right. Right.
Q Okay.
A But I would comment that what that statement must mean is that if there was any tilt, it was very small.
Q Okay. And the reason that you cited to these papers in your Denali section was to note that Denali can fracture?
A Yes, that's correct.
Q Okay. Let's talk about your water hammer effect --
A Okay.
Q -- issue for a moment. And that relates to potential leg fractures, as I understand it, with clot hitting them?
A That's correct.

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Q All right. And I think you talk about this at page 9 of your other report, your big report.
A Page 9?
Q Of the main report. Yeah.
A Oh, you mean in the summary. I see.
Q Yeah, in the March report. I think it's at page 9. We're going way backwards.
MR. O'CONNOR: Which report?
MS. DALY: His original March 17 report, at -- in paragraph 4 on page 9.
THE WITNESS: Correct.
BY MS. DALY:
Q Okay. Now, what analysis have you done to quantify -- well, to ascertain that this water hammer effect, as you describe it, occurs?
A Well, can I make one comment, first of all, which is that I interpret this water hammer effect to encompass the arrival of a blood clot that simply pushes the filter because of its arrival. In other words, there's something driving the blood clot, there's -- the clot arrives at the filter and it has to push the legs to make room for itself as it inserts itself into the filter.
Q But it doesn't keep coming down and

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hammering, does it?
A Well, no, it may not -- hammering may not be the right wording to use in terms of implied severity, but it is possible, because of the pulsatile flow, for that blood clot to continue to push multiple times on -- on the clot -- sorry, on the filter.
Now, there's -- there's another model that I discuss which is perhaps more clearly the water hammer effect, which is what you get in pipes in houses when you hear banging in the -- in the pipes, where you shut a faucet off and the motion of the water is arrested very suddenly and that generates a very high pressure that impinges on the valve that you've just closed. And that is another aspect of the situation that I'm including in my broad meaning of the water hammer effect.
Q And to analyze this what we've called water hammer effect, that's really a dynamic condition?
A Yes, it is.
Q Okay.
A Yes.
Q Did you do an analysis with a dynamic analysis of that potential condition?

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MR. O'CONNOR: Form.
THE WITNESS: Well, that's what my water hammer analysis is, that it's based on fluid moving in a -- in a what I will call a vena cava.
BY MS. DALY:
Q Okay.
A It's a -- it's a tube. And you suddenly stop the motion of that water, and balance of momentum tells you how high the pressure goes as a consequence.
Q So do you -- do you -- do you assume the size of the clot that's necessary to have this effect?
A It -- it would have to occlude the filter.
Q Okay. It would have to occlude?
A Yes.
Q All right. And then what you've got, going back to your -- your plumbing example, you got so much of a hair clot in your plumbing that you have really no water coming past?
A That's correct.
MR. O'CONNOR: Form.
THE WITNESS: Yes.
BY MS. DALY:
Q All right. And so have you seen any cases

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in this litigation where the patient had an occlusion?
A I'm not aware of that.
Q Okay. And do you know how often an occluded Bard IVC filter occurs?
A I don't know.
Q Okay. All right. Would -- would the water hammer effect, if it occurs, lead to fracture in your view or one of the other complications?
A Well, it's going to contribute to fracture, although it may dislodge the filter and, therefore, cause it to migrate, or it could distort the filter so much that it either is able to tilt or it may not even function well as a clot traffic device. So although I -- so there are other possible consequences to the effect of the water hammer event.
Q Let's talk about tilt for a minute.
A Yes.
Q If you go back to your March report, it's in your big report, at page 10, the first thing you talk about there is very top of the page, paragraph 5.
A Yes.
Q "The filter is unstable after

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implementation in the vena cava, and it is very likely that it will always tilt."
A Correct.
Q To which Bard filters does this opinion apply?
A Well, it applies specifically to the -- I think it's the G2 that I did -- no, can I revise that answer?
Q Yeah. Of course.
A It applies to all of them.
Q Okay. Even the ones with anchors, like Meridian and Denali?
A Yes.
Q How much tilt are you talking about when you say they will always tilt?
A A small amount. Measured by 1 or 2 or 3 degrees.
Q Okay. Do you know if there's any clinical significance to a 1 to 3 percent -- 1 to 3 degree tilt of an IVC filter?
MR. O'CONNOR: Form.
THE WITNESS: I'm not aware of any clinical significance.
BY MS. DALY:
Q Okay. Have you done any analysis to

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determine what a tilt in the amount of 1 to 3 degrees might do to contribute to strains or loading on the filter?
A Yes. I -- I used an estimate based on the angle of tilt to calculate what tilt can do to the level of strains involved, and it's proportional -- not directly proportional but the bigger the tilt, the bigger the effect.
Q And which effect is the tilt going to -- what is the tilt going to effectuate, first of all?
A It's going to -- it's going to raise what are called the alternating strains that contribute to fracture.
Q How about perforation, does it -- how does it relate to that?
A I -- it's my assessment that a small amount of tilt will set off an asymmetric response of the -- of the filter and can lead to tilt occurring, because -- because the --
Q Tilt or --
A Sorry, what was the question?
Q More tilt?
A Sorry, what was the question? Oh, sorry, yeah, I misstated my answer.
Q Yeah.

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A Sorry. So it is my assessment, from the mechanics, that a small amount of tilt will generate an asymmetric loading in the sense that one of the arms will apply a bigger force to the wall of the vena cava than other ones, which will generate more tendency for it to perforate the vena cava wall, and then that can ultimately contribute to tilting occurring.
Q And what -- what low amount of tilt have you analyzed in reaching your conclusion that a low degree of tilt will set that in process?
A I haven't analyzed any level of tilt in that sense.
Q Okay.
A I've simply used the deduction that the loads on the legs will not be the same and, therefore, one of them is going to -- it's likely that one of them will -- the one that's more heavily loaded will perforate the wall of the vena cava more rapidly than the one that's lightly loaded.
Q But to model that, a 5 degree tilt to the left will add X amount of strain to struts on the left or the right, you have not done that?
MR. O'CONNOR: Form.

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THE WITNESS: Well, I think there's -- could you repeat the question.
BY MS. DALY:
Q Yeah.
So what I'm trying to figure out is have you done an analysis that looks at "I'm going to start at 5 degrees of tilt," let's just say, "and I've analyzed it, I've done modeling that tells me that 5 percent" -- "5 degrees of tilt to the left, you will see strains in X, Y, Z places in the filter of" --
A So --
Q -- "a certain amount"?
A -- you're asking me about the strains that contribute to fatigue.
Q Sure.
A Okay. So I did a calculation and I recall that the angle of tilt I assumed was 45 degrees, so that's the only direct calculation that I've done. But the formula involved can be used to compute the strains that would be associated with any level of tilt, including much smaller values.
Q To bring about fatigue?
A To bring about fatigue.
Q So then let's back up and I'm going to ask

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you the question. Have you done the same kind of meddling -- modeling, not meddling -- modeling, to look at any certain degrees of tilt and be able to tell us what force that puts on struts that would contribute to perforation, for example?
MR. O'CONNOR: Object to the form.
THE WITNESS: I haven't done any numerical calculations regarding that.
BY MS. DALY:
Q You've basically done a deduction, you deduced that?
A Exactly.
Q All right.
A Although I should comment that Dr. Briant does a calculation in which he looks at the loads applied by the feet -- filters that have tilted and finds that in the tilted filter the loads applied by the -- one of the -- at least one of the limbs of the tilted filter is higher than the loads applied in the case of the untilted filter.
Q But how that then contributes to occurrence of perforation or progressive of perforation, you haven't looked at that?
A I haven't looked --
MR. O'CONNOR: Form.

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THE WITNESS: -- directly at it, but it's my assessment the higher the loads, the more likely perforation is to occur and the more rapidly it is likely to occur.
BY MS. DALY:
Q And I have to ask this question for my record, but you've developed no test to bench test that deduction or hypothesis, that certain degrees of tilt will cause perforation in certain places to certain degrees, right?
MR. O'CONNOR: Form.
THE WITNESS: I've -- I've developed no test to test that hypothesis or that theory. I would -- I only point to the prevalence of the behavior in regard to other implants and other tissues that is a common observation.
BY MS. DALY:
Q All right. Let's look at your March report, page 13, the paragraph just above the 4.2 section.
A Yes.
Q And it says "A conclusion that can be drawn from the above," we'll get there in a minute, "is that the likelihood of fracture due to fatigue in the Bard G2 filter is patient-dependent and can

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be influenced by the details of how a normal successful implantation occurred with some patients having an experience in which their G2 filter offers no danger of fracture while other patients are not so fortunate."
Would you explain to me what -- what you mean.
A Well, what I mean is that even -- that even if a filter is implanted in a successful manner, and that's something that I would leave to medical experts to -- to define, but what I'm saying is that the implantation itself does not directly cause any complications, that there are features of the behavior, features of the -- of the results, that can occur because of differences among patients just because of their different physiology, which is a range of -- of -- of features that we've discussed already --
Q Okay.
A -- that is -- is normally come across in populations of patients, and that some of those physiologies, some of -- in some cases it will lead to negative consequences and other cases it -- it can lead to situations which are quite benign.
Q And that's what we've seen in looking at

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the cases that you've seen in this litigation and medical literature and other things, that there's a range?
A That's correct.
MR. O'CONNOR: Form.
BY MS. DALY:
Q Okay. So have you done any analysis to determine what percentage of people with Bard filters have conditions that meet your assumptions?
A Oh, is that the question?
Q Yeah. Is it 1 percent? 99 percent?
A I have done no such study.
Q Okay. So you don't know?
A I don't know.
Q And have you found in the cases you've looked at and the work you've done whether there's any predictability of failures in any particular type of person, type of situation?
A Well, I'm always looking at worst-case conditions, and so the question of predictability is really not the point to be made but, rather, that having identified worst-case conditions, that will those worst-case conditions, are they -- are they probable in terms of causing failures of the filter. And, therefore, I've not looked at how

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quickly are the rates at which these negative consequences will occur.
Q And have you -- have you looked to determine or have found from medical experts or literature that there are in fact persons who -- with Bard filters who fall in the worst-case scenario?
MR. O'CONNOR: Form.
BY MS. DALY:
Q In other words, they're people that those things are going on with?
MR. O'CONNOR: Form --
THE WITNESS: Well --
MR. O'CONNOR: -- and foundation.
THE WITNESS: Well, with Bard filters, no, I haven't made that assessment.
BY MS. DALY:
Q Nor -- nor have you assessed what percent of people with Bard filters could fall into the worst-case scenario?
A No.
MR. O'CONNOR: Object to the form.
THE WITNESS: I haven't made that assessment.
MS. DALY: What time is it?

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12:45 MR. O'CONNOR: .
MS. DALY: Do you want to eat something?
THE WITNESS: Might as well have some lunch.
MS. DALY: Yeah. Why don't we stop a minute and have lunch. We're making -- let's go off the record.
THE VIDEOGRAPHER: This is the end of Media No. 2. We are going off the record at 12:46.
(Lunch recess taken.)
THE VIDEOGRAPHER: This is the beginning of Media No. 3. We are back on the record at 1349.
BY MS. DALY:
Q Dr. McMeeking, let's talk about perforation for a minute.
A Okay.
Q Can you summarize what -- what are the causes of perforation in the Bard filter that you're aware of?
A Well, I covered that in my report so -- so there are sections where I look at the issue of what would drive perforation, and those issues are the force that the leg applies to the wall of the vena cava and the size of the -- of the -- of the limb because that controls the pressure that the

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limb will apply against the vena cava wall. And that's covered in my report.
Q Is there any difference in contribution to perforation between arms and legs or in mechanisms by which they do it?
A Well, the mechanisms are the same, and as I think I say in my report, the force that the arms apply to the wall of the vena cava are greater than the forces that the legs apply, and, therefore, depending on the extent of the area of contact, it is likely that the arms will perforate the wall of the vena cava to a greater extent than the legs, although I expect both the legs and the arms to perforate the wall of the vena cava.
Q Did you determine any catient -- patient-specific conditions that would make a particular -- that would make a particular patient more or less susceptible to perforation?
A Can you clarify that question. What -- what --
Q Yeah.
A What contributions are you thinking of?
Q In anything that you have identified that you think impacts whether a particular individual will be more likely to have perforation or less

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likely.
A Well, the -- the size of the vena cava I expect play a role because the smaller the vena cava, the bigger the force that the filter will apply to the walls of the vena cava. There are other aspects of the attributes of the tissue in the vena cava wall that I would expect to play a role in determining whether or how much perforation will take place, and those are to do with just the properties of -- of the -- of the tissue.
Q Have you read any medical literature identifying any types of people in patient populations that are more susceptible to perforation than others?
A I believe I have, but I don't recall exactly the details of that situation.
Q And you have taken no data from that type of literature to try to analyze it or do any modeling with it; is that right?
A That -- no, I haven't done that, because what's most important is the observation that the limbs of the Bard filters do perforate the wall of the vena cava.
Q Do you hold the opinion that Bard filters perforate more than any other IVC filters on the

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market?
A I -- I don't have that opinion. I mean, I don't have any opinion on that one way or the other.
Q All right. Now, we've talked several times already this morning about some of your criticisms of Bard's testing of filters, correct?
A Correct.
Q All right. Have you determined, with respect to any of Bard's testing that you're critical of, that had Bard tested with different protocols, the test results would have revealed something different?
MR. O'CONNOR: Form.
THE WITNESS: I'm not quite sure what you mean by have I done anything to determine that, but what I've done is that I've identified the nature of tests that would be more revealing of the performance of -- of the filter and, therefore, would be more informative than the tests that Bard did on the filters that they were intending to -- to market.
BY MS. DALY:
Q And then beyond that, have you taken any step to verify that those different tests would in

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fact show you something different more --
A Well, I haven't done any tests but I've considered the mechanics of what would occur in the tests, and that leads me to conclude that there would be -- you would expect to see significant or at least substantial differences between the behavior in the tests that I've been thinking of and the ones that were actually carried out.
Q But as an engineer, you have seen occasions where testing results actually surprised you, that they didn't meet the hypothesis, true?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: That does happen from time to time, but of course the steps that one would take then are either to consider whether the tests need to be redesigned or whether the hypothesis needs to be modified so --
BY MS. DALY:
Q Right.
A -- there's a step forward that needs to be taken. And I don't think Bard took those steps based on their observations of what was happening to the filter.
Q And you haven't taken those steps forward

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either with your analysis?
A No, I have not.
MR. O'CONNOR: Form.
BY MS. DALY:
Q Okay. Are you aware of any FDA regulations relating to testing that Bard failed to meet?
MR. O'CONNOR: Form.
THE WITNESS: I'm -- I'm not giving any opinion on what they did relative to requirements of the FDA.
BY MS. DALY:
Q All right. Thank you.
Are you going to provide an opinion that Bard had a higher rate of any particular type of complication relative to other filters?
MR. O'CONNOR: Form.
THE WITNESS: I'm not going to offer any opinion on the relative rates of complications of one filter versus another.
BY MS. DALY:
Q What about one Bard filter versus another Bard filter?
A I'm not going to give an opinion on that because I don't have enough data to truly assess

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the situation.
Q Okay. You're not going to give opinions on your interpretation of medical literature that reports on various incidents of complications then; is that correct?
A I'm not going to give opinions on what's in the medical literature, other than to say that they're consistent with my assessment of the engineering considerations of the filter and that they tend to confirm that the filters are -- have -- are dangerous.
Q Well, let's talk about that a minute. What you -- what you would take from medical literature is that there are reports of, for example, fracture, perforation, tilt and migration in Bard filters, true?
A Yes, that's correct.
Q And you also see medical literature that says that there are perforations, tilts, migration and fractures in other IVC filters on the market, true?
A I'm aware of those reports.
Q Okay. And so what did you -- how are you using medical literature to support a conclusion of dangerousness? That's where I'm --

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A Okay.
Q -- missing you.
A Well, I'm observing in the medical literature that these complications occur with the filter and that those complications do present dangers to the -- to the patients, such as a fracture damaging an adjacent organ or a fracture leading to a limb that escapes into the heart or the lungs or the pulmonary artery.
Q And I don't mean to do semantics, but you just said that they do cause that. They can cause that?
MR. O'CONNOR: Form.
BY MS. DALY:
Q Fair?
A Can you repeat the question, please.
Q Yeah.
You used the word that they -- that these complications do cause patient events or patient symptoms. Isn't it more correct to say they can, they don't always?
MR. O'CONNOR: Form.
THE WITNESS: They -- they can generate patient symptoms.
BY MS. DALY:

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Q And you've seen literature that reports that they can be asymptomatic, true?
A I'm aware of that literature, too.
Q Okay. Is there any medical literature that we have not discussed thus far today that you rely on for any of your opinions in the case directly? And there's one that's sitting in front of us that we haven't talked about. It looks like that's an engineering --
A Yeah --
Q -- rather than --
A -- that's the materials engineering paper. Yeah.
Q Okay. Any other medical literature that I may have missed?
A Not literature in the sense of published papers, but of course there's the expert reports --
Q Right.
A -- in -- in the various cases.
Q And what do you rely on from any of the expert reports that we haven't talked about thus far? I know what you've relied on from Richie. What other ones --
A Well, from --
Q -- you've taken anything from?

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A From Dr. Hurst to Dr. Muehrcke, I rely on observations of what happened to the filter in terms of -- of complications and negative events that took place, such as fracture, tilt, perforation and migration.
Q And are you talking about the ones that they submitted in the Bellwether cases?
A Yes, that's correct.
Q Okay. And we'll get to that.
Anything else?
A No, not that I can recall.
Q Okay. So while I remembered this document lying in the middle of the table, let's talk about this and what this relates to vis-a-vis your opinions. I'm marking --
MR. O'CONNOR: Let me just get a clarification. Are you asking him about any literature or reports not mentioned in his reports that he prepared here?
MS. DALY: No, I'm asking him whether there's anything else that he relies on for his analyses today.
MR. O'CONNOR: Separate and apart from what he talks about in his reports, right?
MS. DALY: Yeah. He has some things in

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his report; for example, he'll -- he's got some medical literature in here that he just told me he doesn't really rely on, it has to do with rates and stuff, so...
MR. O'CONNOR: Well, I...
MS. DALY: I don't think we're missing.
(Whereupon, Deposition Exhibit 17 was marked for identification by the Court Reporter.)
BY MS. DALY:
Q Here, this -- this that I've marked as Exhibit 17 has got Robertson, "A statistical approach to understand the role of inclusions on the fatigue resistance of superelastic nitinol wire and tubing," published in 2015.
Could you tell me what that -- what you rely on that for.
A Well, I rely on it because there are some experimental data in here that relate to the fatigue properties of nitinol --
Q Okay.
A -- and specifically to nitinol wire. And the reason that I'm talking about it is that Dr. Briant says that this paper shows that the fatigue limit for nitinol can be higher than the

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difference between the upper plateau of the transformation stress strain curve and the lower plateau of the transformation stress strain curve, and I studied this paper and looked at the data and there's two things that I should say about it.
One is that the data on nitinol tubes that are turned into what is called a diamond specimen, those experiment -- and the experiments are done in those diamond-shaped specimens, those experiments have to be interpreted through calculations, and, therefore, it's quite uncertain in regard to the accuracy of the results that are presented as a consequence of the calculations which are carried out.
In other words, it's -- it's entirely feasible and I think likely that the calculations are giving a misleading result for what goes on in the strains that are experienced by the -- the specimen during the test.
Q Whose calculations are misleading?
A These are calculations carried out by the individuals who are associated with doing the experiments.
Q Oh, so in Robertson's paper --
A Yes.

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Q -- he's talking about that?
A Yeah, Robertson --
Q Oh.
A Robertson carries out some of those calculations for the data in the experiment with results such as Figure 3, illustrated, and uses those results to interpret the experiments which are carried out on specimens of a similar shape. And what I'm saying is that those data are, in my view, unreliable because the results can be -- the results as presented can be erroneous because of errors in the calculations. The --
Q Okay. So --
MR. O'CONNOR: Hold it. Let him --
THE WITNESS: -- therefore, the only reliable data, in my view, in this paper is the data obtained by carrying out experiments on wire, which is under what is called tension tension; in other words, you take the wire and you stretch it and then you let it unstretch, and you do that repeatedly to obtain the fatigue data that you need for the behavior of the material.
And because the specimen is very simple, just a wire that's straight and has a round cross-section, the results that you can get from

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the tests are very reliable in the sense of knowing exactly what the strains are during the test?
BY MS. DALY:
Q Because that is a direct test of the widget itself --
A Correct.
Q -- of the material itself?
A Yes.
Q Okay.
A And -- and -- but most importantly, the calculations that you do to obtain the strain are very simple and don't require assumptions about how to do calculations and what should go into those -- those finite element calculations.
So the data on the wire are clean, and when I look at the data on the wire, I find that the fatigue limit for the experiments that they're doing is consistent with the difference in strain between the upper plateau of the stress strain transformation and the lower plateau, which is in contradiction to what Dr. Briant claims and supports my point of view that -- that if you impose strain on the specimen which exceed the difference between the upper plateau and the lower plateau and, therefore, during the test are

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triggering incremental transformation from austenite to martensite and then incremental transformation from martensite to austenite, that the fatigue limit will be -- will be such that relatively rapid fatigue failure will occur if you go above that level of strain.
Q And what you've pointed out about the Robertson paper is that there are other situations in engineering when direct testing on the bench of a device, a product, a material, gets you better real-life answers than doing your calculations, doesn't it?
MR. O'CONNOR: Form.
THE WITNESS: Well, that's -- no, I don't -- I don't agree with that point of view, because although it gives you certain answers related to the behavior of the component itself, it doesn't give you clean and direct information about the nature of the material, which is what you ultimately need to truly understand what is happening in the component that you're designing or constructing or -- or testing.
BY MS. DALY:
Q Do you know of any medical device manufacturer that puts a device on the market based

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on FE- -- FEA work alone without bench testing?
A I -- I know of no manufacturer who does that.
Q Do you know of any medical device that the FDA would clear without having some actual bench testing?
A I'm not familiar with what FDA does in every particular case.
Q Okay. Would you look at your March report, page 25. At the very bottom, paragraph 9.
A Yes.
Q And it is a reference to an analysis by biostatistician Rebecca Betensky?
A That's correct.
Q And then the last sentence on that page that goes on to page 26 is "Dr. Betensky's analysis," and you cite to the report, "shows statistically significant differences between the Recovery and the Simon nitinol," et cetera. That -- that sentence then goes on, right?
A Yes.
Q Okay. Have you read Dr. Betensky's report? Because you didn't mention that this morning. Maybe --
A Oh.

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Q Did you read her report?
A I read it at the time that I wrote this report.
Q Okay. Did you review any of the actual data that she analyzed?
A I looked at tables and other information in her reports. So in that sense I -- I reviewed it.
Q Her Excel sheets, did you --
A No, I didn't --
Q -- review her --
A No, I did not look at her Excel sheets.
Q Okay. Do you know what information her spreadsheets contain or don't contain with respect to information about the Simon nitinol filter versus other Bard filters?
A Well, I understand that the -- her Excel sheets contain information about failures that were identified in Bard and -- well, Bard filters and that the source of some of that information was more data, and so on.
Q Do you know what time frames she had data for -- data from?
A I would need to look at her report to give you a specific answer to that.

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Q Okay. If I tell you that she had data on the Simon nitinol from 2004, do you know that one way or another?
A I --
MR. O'CONNOR: Form.
THE WITNESS: I don't know that information, but I could establish it by reviewing her report.
BY MS. DALY:
Q Well, it -- that's fine.
You did not perform any of the biostat- -- biostatistical calculations that went into her report, true?
A No, I -- yes, that's true, I did not carry out any of those calculations.
Q And you did not independently verify her work?
A No.
Q Did you provide her with any information that she used in her report or that she considered --
A No --
Q -- as far as you know?
A -- I provided her no information.
Q Have you talked to her about the report?

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A No, I have not.
Q When you say at the top of page 26 that she found -- you have to go back to 25, that she found statistically significant differences between the Recovery and the Simon nitinol filter and then between the Simon nitinol and the other Bard filters, what do you mean by "statistically significant differences"?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: That -- I mean that the differences in the numbers involved were put through tests by her that analyzed the statistical distributions and the differences and the comparisons and indicated, in the cases that I've identified, that these -- these deductions made from those statistics by her were meaningful in that they were identifying real differences in the performance and rates that were observed in the various filters.
BY MS. DALY:
Q They were showing lower numbers of reported incidents of fracture in Simon nitinol than the other filters?
A Yes, that's correct.

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Q Okay. Was it just fracture that you were looking at or that -- that you rely on in any way in the report?
A Well, the -- so there's statistical differences among the filters compared to the Simon nitinol and not just the fracture results but in some other of the negative phenomena as well, but I would have to review the document to -- the report to identify that explicitly.
Q And in what -- in what way does Dr. Betensky's information support any conclusion that -- or opinion that you have in the case?
MR. O'CONNOR: Form and foundation.
THE WITNESS: Well, it -- it confirms and is consistent with my analysis, confirms in the sense that it's consistent with my analysis in that the Recovery, the G2, the Eclipse and the S- -- and the Meridian, and to some extent the Denali, are subject to rates of failure which are greater than the Simon nitinol filter and that that is consistent with my comparative assessment of the Simon nitinol filter compared to the other filters in the Bard line of products.
BY MS. DALY:
Q Right. And we're going to get to the

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Simon nitinol just a minute.
Do you know who Dr. Thisted is?
A I -- I understand that he is a biostatistician at University of Chicago, but that's all I know.
Q Okay. Have you read his report --
A I --
Q -- that he did for Bard in this litigation?
A I have not read that report.
Q Do you know what his opinions are about Dr. Betensky's opinions?
A Since I haven't read the report, I don't know.
Q Do you know that Dr. Betensky was calculating -- whether she was calculating risk ratios or reporting risk ratios?
MR. O'CONNOR: Form.
THE WITNESS: I would --
MR. O'CONNOR: Foundation.
THE WITNESS: I would need to review the document to be sure which -- which parameters she was reporting.
BY MS. DALY:
Q Do you know what the differences between

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those things are, a risk ratio and a reporting risk ratio?
A I'm not familiar with that difference.
Q Okay. Did Dr. Betensky do any work with respect to the probability of the occurrence of any complication in a Bard retrievable filter that you recall?
A Could you clarify that question.
Q Yeah.
Did she do any statistical analysis of the probability, the likelihood, of which any complication would happen in any particular Bard retrievable filter?
MR. O'CONNOR: Form and foundation.
THE WITNESS: In an implanted --
BY MS. DALY:
Q Yes.
A -- filter in a patient?
Q Yes.
A I would have to review the document to be sure, but I'm not aware of that analysis.
Q All right. Let's talk about your SNF analysis, which really comes in your rebuttal report of 5-11-17, which we have marked as Exhibit 4.

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MR. O'CONNOR: I'm sorry, which one is that?
MS. DALY: It's his rebuttal report, May 11, 2017.
MR. O'CONNOR: Thank you.
BY MS. DALY:
Q Did you have the opportunity to examine an exemplar Simon nitinol filter?
A I have a Simon nitinol exemplar in my possession now.
Q Okay. When did you get that?
A Last week.
Q Who sent it to you?
MR. O'CONNOR: Hold on.
MS. DALY: Who sent it to him? Did he get it from you?
MR. O'CONNOR: He got it from I believe somebody, but is that necessary to know?
MS. DALY: Yeah, I want to know if he got it from a plaintiff's attorney, if he got it from a friend, if he got it from somebody at the drugstore.
MR. O'CONNOR: I believe he -- he requested it from attorneys.
BY MS. DALY:

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Q You received it from an attorney?
A I received it from an attorney.
Q Okay. And you had not had that before?
A No, I had not had an exemplar in my possession before.
Q Did your examination of the exemplar change anything that you've written in the rebuttal report about the SNF --
A No.
Q -- or how it compares --
A No.
Q -- to the Bard filters?
A No.
Q All right. You -- to do your rebuttal report, you looked at the engineering drawings for the SNF --
A Correct.
Q -- is that true?
A That's correct.
Q What else did you look at?
A I looked at -- well, I was looking at the 510(k) for the Recovery --
Q Okay.
A -- and it told me various things to do with changes that were made, such as the diameter

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of the -- of the limbs and the material of which the filters were made, and so that enabled me to draw conclusions about how to compare the Simon nitinol with the other filters.

Q Okay. And the Simon nitinol filter is basically -- got a round -- a rounded dome with petals. You've got a good diagram of that at the back of the report. And then legs on the bottom, six legs?

A That's correct, yes.

Q Okay. What design characteristics of the Simon nitinol filter make that filt- -- made that filter not retrievable percutaneously?

MR. O'CONNOR: Form and foundation.

THE WITNESS: Well, I'm not entirely sure because I've not investigated that situation, but it's my surmise that it is the extent of -- of connection among the wire -- wires of the petals and the vena cava wall which presents more material that can bond from the vena cava wall to the petals of the -- of the filter, and so that will generate a robust connection between the filter and the vena cava wall.

BY MS. DALY:

Q Did --

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A And also the -- the legs do seem to perforate to some extent through the wall of the vena cava, and I -- I'm assuming that that would present complications upon retrieval.

Q Did you investigate whether once deployed that petal formation was at all difficult to slim back down, if you will, to crimp it into a sheath for retrieval?

A Well, I made an estimate of the stiffness of those petals, and so although I didn't make a comparison with what is required to put it into the delivery sheaths, I -- I did have the analysis at hand from which that could be undertaken.

Q And you determined they were pretty stiff?

A They're -- they're

Q Not to use a good engineering term.

A Yeah, they're -- they're stiff compared to the Bard arms -- sorry, the arms on the Recovery, the G2, and other subsequent filters.

Q And the legs are stiffer than the Recovery and other retrievable --

A Yes.

Q -- Bard filters as well?

A That's correct.

Q Okay. You understand that the -- that

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Bard's purpose in developing the Recovery filter was to provide for a filter that could be percutaneously retrieved?

A I understand that that's the case, but they were developing an optional filter which meant that it was represented as being usable as a permanent filter as well as having the option of being percutaneously removed.

Q But so you do understand it had the dual --

A I understand it has --

Q -- the dual goals?

A -- that dual target.

Q Right.

And did you understand that an important benefit to patients in a retrievable IVC filter is the fact that it can be retrieved?

A Well, I'm -- I'm not a doctor and I'm not a medical expert so I don't know that in a detailed way, but from a position of someone who may be a patient, it makes sense that one would want to have the implant out if that is possible.

Q Okay. Now, in your -- in your rebuttal report where you're comparing the Simon nitinol, you compare it to the G2 and Recovery filters,

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correct?

A Can you remind me of where I do that.

Q Yes. Let's see. Pages 8 through 16 is where you discuss the Simon nitinol. And if you look at the bottom of page 9, my impression is that you're looking at it comparatively to Recovery and G2 throughout and that you -- and that you didn't do specifically a head-to-head comparison of it to the later generations.

MR. O'CONNOR: Form.

THE WITNESS: I didn't do that specific comparison but that's because the characteristics of the later generations would be similar to the Recovery and the G2, and, therefore, at the level I was doing that comparison, it was not a significant aspect of what I needed to consider.

BY MS. DALY:

Q Okay. I understand that's your -- that's your opinion.

Okay. So what your -- what your report concludes about the SNF is a couple of things, and I'm trying to see whether I got this from a place where you summarized them all together or they're spread out.

All right. Let's start, first of all, on

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page 9 at the second full paragraph where you say "The shape of the petals." Do you see that?
A Oh, the second full paragraph.
Q Yeah.
A I see it, yes, yes.
Q "The shape of the petals is quite complicated, so to estimate their stiffness to radial compression I simply treat them as two arms of a length of 16 millimeters joined together."
Okay. Will you explain to me what you mean by that. How did you do that analysis of stiffness of the petalled shape?
A Well, I mean that I approximated them as straight wires that were in the form of a loop but the wires were -- the two wires -- sorry, I should start again because I became imprecise.
So I represented the petal as a single wire that has the shape of a loop but the loop is such that the two wires are parallel to each other except at the end where they meet together in the form of a -- of a junction adjoined, a joint.
Q Okay. So -- so with that assumption, you determined their basic stiffness?
A That's correct.
Q Okay. Vis-a-vis the Recovery or the G2,

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you say that "The radial compression for the SNF" -- we're talking about the petal portion?
A Yes.
Q Okay. -- "is 10 times that of a single arm of Recovery and approximately 18 times that of a single arm of the G2," right?
A Yes, that's what I -- that's what I wrote.
Q But what you're comparing is the whole petal to one Recovery arm for comparison of stiffness?
A That's correct.
Q All right. So if you go down below that a couple more lines after you've talked about the 18 times the single arm of the G2 --
A Yes.
Q -- you go down four lines and it says "I find that a single petal of the SNF is approximately 50 percent stiffer than a single arm of the Recovery or G2."
What -- what is the definition of the single petal?
A Well, single petal is the loop that you can see in this diagram, although it's maybe unclear at the level that it can be seen, but a loop is formed by the wire coming out of the top

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bushing, it goes out in a radial direction more or less, there's a segment which is almost circumferential in -- in regard to the shape of the vena cava which -- by which I'm using to define circumference.
Q Okay.
A And then the loop comes back in towards the center of the filter and enters the lower bushing.
Q Okay.
A So that's what I'm considering to be the loop.
Q So for the first comparison that you did where the petal stiffness was 10 times that of a single arm of Recovery and 18 that of a single G2, are you able to take this yellow highlighter and draw for me what you were comparing off of the SNF against the Recovery or the G2 arm?
A I'm sorry, could you repeat that.
Q Yeah.
I'm trying to figure out what you are defining as the petal of the SNF where you say here on page 9 "A single petal of the SNF during radial compression is 10 times greater than that of a single arm of the Recovery and a single arm of the

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G2."
A Okay. I'll do that by putting some letters on the --
Q Great.
A -- diagram.
Q Perfect.
A A, B, C, D.
Q Perfect.
A And the -- is it going to be visible using yellow?
Q Well, you know what? You can have a pen. Do it any way that makes sense.
A So a single petal starts at A.
Q Okay.
A Comes down to B.
Q Okay.
A Runs around to C.
Q Oh, okay.
A And then goes down into the other -- the lower bushing at D.
Q All right.
A So A, B, C, D is -- is that loop.
Q So it goes to the left of the cap and to the right of the cap, that's a single petal?
A That's correct.

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Q All right. So when you mentioned single petal a couple of sentences down, that's the same thing you're talking about where you say "A single petal of the SNF is approximately 50 percent stiffer"?
A Yes.
Q Okay. Then you say "If endothelialization constrains rotation of the wire where it's bonded to the wall of the vena cava, all stiffness will increase by a factor of 4."
What do you mean by that?
A Well, I mean that if you have an end to the loop or the Bard -- sorry, the G2 or Recovery arms and you compress it by the action that the vena cava would apply to the filter as the reduction -- as the diameter of the vena cava reduces, if you have an end of those features which is capable of rotating as that deformation takes place, you would get a certain value of the stiffness where the stiffness is the ratio of the force that you apply to the displacement which is imposed.
Q Okay.
A Now if you constrain the rotation so that the end both moves according to the vena cava wall

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but does not change its orientation relative to the vena cava wall, then the stiffness will be four times, which means that the force will -- that you apply will be four times that which you got when you did not constrain the rotation.
Q Okay. And that stiffness in the petal area may make folding that back down, once it's in the patient to put it in a sheath for retrieval, more difficult?
A It would mean --
MR. O'CONNOR: Form.
THE WITNESS: It would mean --
MR. O'CONNOR: Foundation.
THE WITNESS: It would mean that you have to pull on the filter with a bigger force relative to the Recovery catheter to put into that Recovery catheter.
BY MS. DALY:
Q And what that might translate into insofar as patient injury, you do -- you have not done an analysis of that?
A I have not done an analysis of that.
Q All right. Now, this is what I wrote down about your conclusions from the SNF report, and I want to talk about these separately and tell me if

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I'm missing something.
The first one I wrote down was that it was more resistant to migration than the Bard's retrievable filters. Is that a conclusion that you make?
A Yes, that's correct.
Q Okay. And in what direction is it more resistant to migration?
A Well, my engineering assessment would indicate that it's more resistant to migration after it's been firmly implanted in the vena cava, that it's more resistant to migration in both the caudal and the cephalic direction.
Q Okay. Are you saying that it will never migrate?
A No, I'm not saying that, no.
Q Is it principally the stiffness of the petals that contributes to the migration resistance in this or is it more than that?
A Well, I think it's -- I think it's a combination of the stiffness of the petals and the stiffness of the legs.
Q Is there anything about any other dimensions of the Simon nitinol, diameter of wire, length of -- length of anything, height of the

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filter overall, anything like that, that contributes to migration resistance?
A Well, the diameter of the wire controls the stiffness of the wire -- of the components that are made from the wire, so that has a -- that has an effect, which I've already alluded to in the -- in the answers I just gave.
Q Okay.
A The length of the petals and the lengths of the legs also contribute to controlling the stiffness, so those would contribute as well. And I'm not sure if I can identify anything else, but those were -- those would be the things that I would identify.
Q Did you do any analysis of how one would make changes to either the petal dome or the legs of the SNF to allow it to be retrievable?
A Can I augment my answer of just a second ago? The -- the diameter or the span of the petals and the span of the arms -- the legs relative to the diameter of the vena cava would contribute to the forces which are involved and, therefore, contribute to the question of whether migration is or is not likely in the Simon nitinol filter.
But to move on to your subsequent

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question, I didn't make -- do any analysis to look at what changes might -- what changes -- what impact they would have on the behavior of the -- of the filter.

Q Including the last thing that you just mentioned to me, the difference in span?

A Yes.

Q How that might have to be re-engineered to allow for retrieval?

A I did not look at that.

Q Okay. The next thing that I saw from your report was that the design of the SNF legs make them more prone to perforation than the struts of the Recovery and the G2?

MR. O'CONNOR: Where are you looking at in the report?

BY MS. DALY:

Q The different ones start on page 11. Your first one was migration, and then the little B on page 11 is where I'm reading from right now.

I'm sorry, that's not where I got it from. Go to page 13. I apologize. B on page 13.

A Yes.

Q So I think what you concluded there was that the legs of the Simon nitinol were more prone

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to perforation of the vena cava wall than the Recovery or G2?

A In the legs of the Recovery and the G2.

Q The legs. Okay.

Did you look at any medical literature about the Simon nitinol to confirm whether you were correct that there was more -- that there was a fair amount of perforation from the legs of the Simon nitinol?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: I -- I didn't look at papers to specifically ascertain that information, but I did read some papers that indicated that perforation by the legs of the Simon nitinol filter do occur.

BY MS. DALY:

Q Are you familiar with the Poletti paper, for example, where he says that legs perforated 95 percent of the time and 76 percent of the time to --

A Yes, I --

Q -- to organs?

MR. O'CONNOR: Hold it. Hold it. Object to the form of the question.

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Why don't you get the Poletti article and take a look at it. Do we have it?

THE WITNESS: I don't have it.

MR. O'CONNOR: Do you have --

BY MS. DALY:

Q Do you agree that it says that? Do you remember it saying that?

A May I look -- may I look at the paper --

Q Of course.

A -- to ascertain that?

Q Of course. Let's make this 18.

(Whereupon, Deposition Exhibit 18 was marked for identification by the Court Reporter.)

THE WITNESS: Thank you.

BY MS. DALY:

Q And if you look at the abstract, that might help you find it quickly.

A In the abstract is it says "A CT examination showed that the struts of the SNF have penetrated the vena cava in 95 percent."

Q And then does it say something like 76 percent?

A "And where in contact with adjacent organs, in 76 percent."

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Q Okay. All right. So is the -- in your analysis of the Simon nitinol, is the perforation of legs in the Simon nitinol related to the dimensions of the leg, the stiffness of the legs, or something else?

A Well, in my engineering assessment, it's a combination of -- of the stiff -- of the dimension of the leg or the length of the leg and the material from which it's made.

Q So what would one have to do to engineer the legs of the Simon nitinol to diminish perforation?

A One would perhaps lengthen the legs or make them smaller in diameter or one may choose a different material that is more compliant than the nitinol from which it's made.

Q Okay. But again, you have not tried to do any finite element analysis or any testing to determine how one would re-engineer that, true?

A I've done no calculations or tests --

Q Okay.

A -- in that regard.

Q The next one on page 14, C, is you're talking about the high stiffness of the SNF petals and legs and that relationship to tilt. Will you

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tell me what your -- what you found.
A Well, as it -- as is written in the report, the stiffness of the petals means that when you compress them into a vena cava to achieve a specific diameter of the petals, that the strain energy, the work that's stored in the petals, is higher than the work that would be stored in the arms of and the legs of the Recover- -- yeah, the arms and the legs, and I should include the legs in the Simon nitinol filter as well.
Q Okay.
A But the work done -- the work stored in the arms and the legs of the Simon nitinol filter is greater than the work stored in the arms and legs of the Recovery and G2 filters where they've been put through the same reduction in size.
Q And what does that mean?
A It means that each component of the Simon nitinol filter has -- in other words, the petals or the legs, has a higher driving force for tilting than the equivalent component of the Recovery and the G2 filter.
Q Meaning it will tilt less or tilt more in your opinion?
A Well, it -- it -- each component will want

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to tilt more but --
Q In the SNF or the --
A In the SNF.
Q Okay.
A But there is a feature of the design of the SNF which is that you have these two bushings with some compliance in between them which allows the top of the filter to rotate relative to the bottom, which means that -- that while there are high driving forces for the tendency to tilt, there is a more forgiving aspect to the filter that enables it to accommodate the tendency to tilt perhaps by the petals alone tilting but not the legs or the legs alone tilting but not the petals.
Q And what accommodation are you speaking of? Meaning that the tilt doesn't have consequences beyond tilting or that -- what do you mean by that?
A Yeah, I mean that the -- that the tilting -- I mean that the tilting would be self-limiting and the -- the driving force would not be as continuous as it would be in the G2 and Recovery filters, and, therefore, the extent of net tilting of the filter is likely to be less in the case of the Simon than in the Recovery and the G2.

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Q Did you do any analysis of the Simon nitinol for tilt and strains on the filter as a result of tilt as you did with the G2/Recovery filters?
A No, I did not carry out such calculations.
Q And the Poletti article talks about there being 63 percent of the Simon nitinols in that study that demonstrated eccentric position. I don't think that's in the abstract, I think I have to go in there to look for it.
A It is in the abstract.
Q Okay.
A It says "Filters were in eccentric position in 63 percent."
Q And I take that to mean Poletti's talking about tilt; is that what you think?
A I'm assuming that there was an identifiable degree of tilt, so there was some tilt and it was big enough that it could be identified.
Q Have you done any analysis comparing the Simon nitinol in whatever amount of tilt it could do to how it would fare comparatively to the Meridian and Denali that have the anchors on them?
MR. O'CONNOR: Form.
THE WITNESS: I haven't done such a

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comparative analysis except in the sense that it is my assessment that the -- did you say the Meridian and the Denali?
BY MS. DALY:
Q Yes.
A The Meridian and the Denali are very similar in shape to the Recovery and G2, and, therefore, some of these features are analogous in the Meridian and Denali in terms of the behavior in tilting.
Q But you haven't done any specific analysis to determine whether the modifications to the Meridian and Denali will have improved resistance to tilt and anything that tilt might cause?
MR. O'CONNOR: Form and foundation. Excuse me. Object to the form of the question.
THE WITNESS: Well, I haven't done any analysis, but I recall the tests that Bard carried out that showed that the Meridian was tilting just as much as the -- I believe it was the Eclipse filter in the bench test that they carried out.
BY MS. DALY:
Q But what were the strains on the legs in tilt?
A I didn't do that calculation.

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Q Okay. And it would be the strains that would drive fracture perhaps?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: It would be the strains that would drive fatigue fracture, yes.
BY MS. DALY:
Q Okay. On page 14, we're still in C but we're in the next paragraph of little C.
A Okay.
Q And it's talking about clot trapping by the Simon nitinol.
A Yes.
Q And tell me what your opinion is about the Simon nitinol's ability to clot trap and tilt versus Recovery or G2?
A You mean to act as a clot trap?
Q Yeah. I thought what you were saying here was you were comparing a tilted Simon nitinol and its effectiveness to still capture clot versus Recovery and G2 in tilt. Did I misinterpret that?
A No, in that paragraph I'm not doing that.
Q Okay. Did you do that analysis?
A I need to look through this to see.

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So as I write in the report at the bottom of page 14 --
Q Okay.
A -- you see there's a sentence that says --
Q Yeah.
A -- "In the design of the SNF as depicted in Figure 2, the clot trap appears to remain effective even after it tilts."
Q Uh-huh.
A "The tilting of the clot trap will not greatly increase any likelihood" -- that's not relevant to what you're asking.
Q Okay.
A So just because of the number and nature of the shape of the petals in the clot trap, it is my assessment that even after it's til- -- tilted, it can remain effective as a device for trapping clots.
Q Did you see any test of the Simon nitinol in tilt and see what the results were with a clot trapping test?
A No, I haven't seen any results of such tests.
Q Okay. And similarly, have you seen those tests for clot trapping effectiveness in the

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Recovery or G2 filter?
A I may have seen those, but I don't recall the results.
Q How far would a G2 or Recovery filter have to tilt to be less effective at clot trapping than a Simon nitinol?
A I -- I don't know.
MR. O'CONNOR: Object to the form.
BY MS. DALY:
Q Then there's a next sentence that -- you just stopped at that semicolon and it says "The tilting of the clot trap will not greatly increase any likelihood of perforation of the caudal wall."
Could you explain that to me?
A Well, I mean that the -- because the contact between the petals and the wall of the vena cava is spread out over a significant length of the perimeter of the petals in the clot trap, that the -- that there would not be a tendency for the shape of the petals to try to aggressively penetrate the wall of the vena cava.
And, in addition, because the forces that are being applied by the petals to the wall would go down when the clot trap tilts, it's my -- that would contribute to the tendency for the likelihood

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of perforation to not increase.
Q Okay. But the endothelialization of the petal-shaped dome into the vena cava in the Simon nitinol creates a stiff element? Am I describing that right? I mean, it's -- it's got a lot of radial force and stiffness --
MR. O'CONNOR: Object to --
BY MS. DALY:
Q -- because of the way that the petal contacts the vena cava wall; is that correct?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: No, that -- that's not the reason it has a high degree of stiffness, it's simply the shape of the clot trap --
BY MS. DALY:
Q Okay.
A -- and how it's composed of wires that would give it its high stiffness.
Q And then does it also endothelialize, this is the petal dome, does it endothelialize into the circumference of the vena cava?
A I don't know that for certain, but it's my surmise that that's what would occur.
Q Would that be something that would also

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make retrievability -- would that be something that would also contribute to non-retrievability of the Simon nitinol?

MR. O'CONNOR: Form and foundation.

THE WITNESS: Yes, that would tend to inhibit retrievability, which is what I said earlier in answer to one of your questions.

BY MS. DALY:

Q Okay. Then you talk about, in section D, I summarize that as you're saying the SNF is more fracture-resistant than the R -- the Recovery or the G2. Is that what you're saying?

A That's what I'm saying, yes.

Q All right. And what features of the Simon nitinol make it more fracture resistant?

A I need to read this first, please.

Q Sure.

A So the contribution that I'm addressing is that it is usually perforation that increases the strains up to levels that become dangerous in the fatigue behavior of the material, and since it's unlikely, in my assessment from the engineering, that the SNF petals are not likely to perforate the wall, therefore it's unlikely that the strains driven by expansion and contraction of the vena

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cava would be driven up to levels that would lead to fatigue failure in -- in relatively short periods of time.

Q And did you do any modeling to show that?

MR. O'CONNOR: Object to the form of the question.

BY MS. DALY:

Q Using --

A I didn't.

Q -- specifically the Simon nitinol and comparing it over.

A I didn't do any modeling directly, although the analysis that I did would enable that kind of assessment.

Q But you have not done that?

A I haven't done it.

Q Okay. And what about the legs of the Simon nitinol, you just talked about your opinion that perforation is a driver of fracture and we've just talked about SNF legs being prone to perforate, so what about them and fracture?

A Well, the -- the perforation process would drive up the fatigue strains, and, therefore, it would make fatigue fracture more likely in the SNF compared to the situation where its legs do not

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perforate the wall of the vena cava.

Q Because there's no difference, in your opinion, perforation in an SNF is going to drive strains, perforation in a G2 or Recovery is going to drive strains, they could lead to fatigue?

A That's true, although I really -- I would like to make -- I should make that assessment numerically, because the geometry and the shape of the legs, for example, make it -- play a role in the exact results that you'd get out of such a calculation. But in -- but broadly speaking, perforation would have the same effect on both models of filters.

Q And you did not do any specific comparison of Simon nitinol design for resistance to any one of the complications versus the G2X with some change to its chamfer, you didn't do that specific comparison?

A No.

Q You did not do that specific comparison with the electropolishing change to the Eclipse?

A No.

Q Nor did you do it with the changes that were brought forward from the Eclipse into the Meridian and its addition to anchors, you didn't do

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that?

A No.

MR. O'CONNOR: Form.

BY MS. DALY:

Q Nor did you do it with the Denali laser cut from a nitinol tube that also has anchors?

MR. O'CONNOR: Form.

THE WITNESS: I didn't do any of those analyses because it's my assessment that those changes did not make a significant difference to the -- to the filters in terms of reducing the danger that they present because of their failures.

BY MS. DALY:

Q Are you giving the opinion that the Simon nitinol is an alternative safer product than the Bard retrievable products?

MR. O'CONNOR: Form.

THE WITNESS: I'm offering the opinion that in the setting of permanent use of a filter, which the Recovery and the G2 and its successors can -- can be used as, that the Simon nitinol is a safer alternative.

BY MS. DALY:

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Q But you would agree that the Simon nitinol will not serve populations of people whose doctors believe they need a retrievable filter, true?
MR. O'CONNOR: Form.
THE WITNESS: I'm -- I'm not offering that opinion. Was that -- could you ask the question again?
MS. DALY: Can you read that question.
(Record read Lines 1-3.)
MR. O'CONNOR: Form.
THE WITNESS: Well, since I'm not a medical doctor and I can't really answer that question properly, but since it's -- since it's represented as a permanent filter, that would suggest that it's not meant to be used in situations where retrievability is -- is advised by the doctor.
BY MS. DALY:
Q The Simon nitinol isn't?
A The Simon nitinol.
Q Okay. Did you make any effort to look at modifications that would have had to be made to the Simon nitinol filter to allow it to maintain what you conclude is low complications rate but make it percutaneously retrievable?

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A No --
MR. O'CONNOR: Form.
THE WITNESS: -- I didn't look at that.
MR. O'CONNOR: Okay. When you get to a place where we can take a quick break?
MS. DALY: Yeah. Almost.
MR. O'CONNOR: Okay.
MS. DALY: This is a good break point.
MR. O'CONNOR: Oh, great.
MS. DALY: Can you tell us what our time is.
THE VIDEOGRAPHER: This is the end of Media No. 3. We are going off record at 1454.
(Recess taken.)
THE VIDEOGRAPHER: This is the beginning of Media No. 4. We are back on the record at 1508.
BY MS. DALY:
Q Dr. McMeeking, have you performed any actual tests on Bard retrievable filters to determine if an interrelatedness of complications actually exists?
A Do you mean a bench test or --
Q Yes.
A -- an experiment of some kind?
I have not carried out any experiments on

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Bard filters.
Q And what analyses have you done that we have not talked about yet today that you claim is a model that would support some interrelatededness of any types of complications?
A Can you point me to where I write that in the reports?
Q No, because I'm -- I'm trying to just do this kind of generally. I guess let me ask it a different way.
You talked -- you talked briefly about perforation leading to fracture.
A Correct.
Q Okay. So let's start with that one. Have you done a model that actually shows that perforation creates a load that leads to a fracture?
A Yes.
MR. O'CONNOR: Form.
THE WITNESS: Yes, I have.
BY MS. DALY:
Q And which of your analyses is that? Just describe which one.
A Well, the beam bending analysis where I consider both the G2 and the Recovery filters, the

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arms of those filters, and I look at shapes which are consistent with different degrees of perforation through the wall of the vena cava and then I calculate the strains imposed on the filter by expansion and contraction of the wall of the vena cava, and then I consider that in the light of fatigue performance of the material.
Q And so that's what I wanted to ask you for each of these connections. So your alleged connection between perforation and tilt, have you done a model of that? And which one of it is? Just point me to which one it is.
A So are you asking me have I looked at perforation that occurs first and then leads to tilt? Is that the --
Q Yes.
A Is that how I interpret the question?
Q Or either -- or either way around.
A Well, I -- I've carried out assessments in which the process of -- of -- of perforation -- I've done calculations where the process of perforation leads to tilt of the filter, so I've done finite element calculations in which that occurs as -- that tilting occurs as a consequence of perforation. And it's in my report.

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And then in terms of the question of tilt leading to perforation, I've considered the elevation of the loads that is associated with the tilt in terms of one leg having a higher -- or one arm having a higher load applied to the vena cava than another, and concluded that that would lead to more rapid perforation of one leg into the wall of the vena cava.

And, in addition, that's supported by calculations that Dr. Briant has done in regard to comparing a tilted and untilted filter in terms of the forces that the limbs apply to the wall of the vena cava.

Q And then with respect to any of your opinions about interrelatedness of one complication to the next, you agree that the relationships may well be patient-specific?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: I would -- I would assess that in each -- in each patient, given the differences in physiology, that different interactions can occur in terms of what the implications or what the consequences of tilt and perforation is on -- in that particular patient.

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BY MS. DALY:

Q And that, for example, perforations occurring at different places in the filter --

MR. O'CONNOR: Object to the form -- form of the question.

MS. DALY: I'm not sure why you're objecting to that.

Q That perforations in different struts in a given filter may result in no increased strains that will lead to a fracture; is that fair to say?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: No, I think in every case, that perforation of one limb will lead to an increase in strains in the filter compared to what you get in an unper- -- did I say perforation?

BY MS. DALY:

Q Uh-huh.

A We're talking about perforation.

So that perforation of one limb would increase the strains in that limb and the limb opposite it compared to what you would get in an unperforated filter, and this would occur whether it's two neighboring filters -- sorry, two neighboring limbs that perforate or three

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neighboring limbs that perforate or any combination of limbs that -- that perforate, because it's the interaction between one limb and the one that's opposite on the clock that determines the degree of strain that will develop as a consequence of the motion of the vena cava wall.

Q And the one that's on the opposite side of the clock, if it's perforating the same amount, what then?

A Well, if -- if the two are perforating on -- if they're opposite each other on the clock, then that is going to give you bigger strains than if one alone on that pair of limbs perforates.

Q But you haven't done any specific modeling to look at the clock and try different sequences of perforating limbs and see what the strains are?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: Other than what I just described, I haven't done that kind of modeling.

BY MS. DALY:

Q Okay.

A But I should say I don't think that that kind of modeling is necessary to make the conclusions I just gave you.

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Q And have you determined an amount of perforation that's required to start to increase the strain?

MR. O'CONNOR: Object to the form.

THE WITNESS: Even a small amount of perforation will increase the strain.

BY MS. DALY:

Q Increase the strain to the point of contributing to a fatigue fracture?

A I haven't -- well, I have in the -- in the calculations that are -- I draw your attention to my report where in one section there are a whole lot of tables and the --

Q We're looking --

A -- tables --

Q -- at Exhibit 2?

A Yes. Exhibit 2.

Q Okay.

A And we're looking at Section -- well, I can do it in terms of page numbers.

Q Yeah.

A We're looking at pages 45 or maybe 44 through --

Q Okay.

A -- through page 53 or so. Yeah, 53. And

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in each of these tables there's a calculation for different degrees of perforation that has taken place for a pair of arms which are on the opposite side of each other on the clock.
Q Right.
A And the resulting strain is in the table, and one can compare the strain in the table with the fatigue limit of the material and when the strain in the table crosses the fatigue limit, then that will begin to induce failures which will eventually happen if the number of cycles of loading occurs to take the material to its -- to its fracture condition as a consequence of the cyclic loading of the material.
Q So this section that's here at 45 that you've just described is where you compare the -- the arms perforating on opposite sides of the clock, if you will?
A That's correct, yes.
Q Okay. All right.
A Yes.
Q And what is the least perforation that you considered, the least amount of perforation?
A Well, I'd have to compare every result and every table, which could take some time. I --

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well, the least --
Q I mean, do you know the range? That's what I'm saying. Do you --
A Well, actually the least perforation I considered was zero.
Q Okay.
A And then --
Q Show me what page is your highest shown.
A Well, in some of the tables I don't actually give the results, so of all the four tables I can't give you an answer, but in the tables where I do give the results, the answer is in Table 2 at the bottom, on the bottom line where the degree of perforation is 3.5 millimeters.
Q Okay. And that's page what?
A Page 49.
Q 49. That's where I am. Okay.
MR. O'CONNOR: How do you take it? Black?
THE WITNESS: Yes, black, please. Thank you.
BY MS. DALY:
Q Have you done any work to look at the probabilities of, for example, fracture in --
(Brief interruption.)
MS. DALY: I forgot what I was saying.

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Can you read what I started to say.
(Record read as follows:
"Have you done any work to look at the probabilities of, for example, fracture in --")
BY MS. DALY:
Q Fracture in a filter that has nothing going on but two perforating arms on opposite sides of the clock to, what was it, 3.5 millimeters out?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: I'm sorry, could you repeat the question.
BY MS. DALY:
Q Yeah.
Have you done any work to look statistically at probabilities of fil- -- of when filters will fracture based on perforations that they have present, tilt they have present, any of the complications?
MR. O'CONNOR: Form.
THE WITNESS: I haven't done statistical assessments of that situation.
BY MS. DALY:
Q Okay. And similarly, you have not done

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any statistical assessment of the probability of a filter that is -- has experienced one complication, let's say perforation, having another complication, let's say tilt?
MR. O'CONNOR: Objection.
THE WITNESS: Can I --
MR. O'CONNOR: Form.
THE WITNESS: I'd like to augment my previous question (sic), which is that if I assume in certain sizes of the vena cava if the perforation continues to the extent that I've assumed, that the probability of the frac- -- the fatigue -- the limb failing by fatigue after a certain number of cycles is very high, and if -- and if you take a large number at a certain stage, over half of those filters would fail.
BY MS. DALY:
Q In a certain amount of time, what does that mean?
MR. O'CONNOR: Object to the form.
THE WITNESS: Can you -- can you tell me what I said.
MS. DALY: Yeah, would you re-read his last answer, because he had something about a certain amount of time.

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(Record read as follows:
"I'd like to augment my previous question (sic), which is that if I assume in certain sizes of the vena cava if the perforation continues to the extent that I've assumed, that the probability of the limb failing by fatigue after a certain number of cycles is very high, and if you take a large number at a certain stage, over half of those filters would fail.")
BY MS. DALY:
Q At a certain number of cycles. What are those -- what's the certain number of cycles?
A Well, it depends on the strain which is involved, and the bigger the strain, the smaller the number of cycles.
Q So you're saying in a given filter, if that given filter has the condition that you've modeled, after a certain number of cycles, that you haven't computed what those are, it's more -- it's 50 percent likely to -- to fracture?
A That's correct.
Q But we don't know what the cycle numbers

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are?
A Well, if we look at the Bard data and we take that as the true reflection of how the material behaves, then that can be used to look at the number of cycles that will give you that 50 percent level of the -- of the limbs failing.
Q So in everybody who's got a perforation to the extent of -- what? What number? What --
A 3.5 millimeters. This number is what would occur if the filter is perforated to the extent that it goes back to its designed shape.
Q So in everybody that has a perforated filter 3.5 millimeters or more outside the vena cava in some number of cycles that you can't compute --
A Well, we have to be careful how we interpret this number, because the 3.5 millimeters is where the elbow is outside of the vena cava, so there's also the -- the lower arm would be outside the vena cava as well, so this is a very large element of the limb outside of the vena cava.
Q Okay. So very large element is outside the vena cava and in a certain number of cycles that you cannot compute, 50 percent of those will fail?

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MR. O'CONNOR: Form.
THE WITNESS: But I said I can compute it.
BY MS. DALY:
Q The number of cycles? What number of cycles then?
A Well, for example, in -- if the number is in a -- is exactly equal to the fatigue limit of the material, then the number of cycles involved would be 10 to the 8.
Q So have you done that type of calculation for any individual person?
A No, I have not.
Q Okay. So you don't have from a real-life person any example of where you followed them through imaging, saw what was happening with perforation or tilt or movement of the filter, put these calculations on it and said "A-ha, they had a fracture"?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: I have not gone through such a process.
BY MS. DALY:
Q Okay.
MR. O'CONNOR: How do you spell "a-ha"?

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MS. DALY: She knows how to spell it.
Q All right. We are going to case-specific.
Starting with Ms. Booker's case. And starting with your report in Ms. Booker's case.
A Okay.
Q All right. You say in your Booker report, page 2, paragraph 1 that, quote, "I have determined to a reasonable degree of engineering and scientific certainty that Ms. Booker's G2 filter experienced all of the failure modes consistent with defects inherent in that filter."
Is that what you say?
A That's what I said.
Q Okay. Then in that same report on page 1, and it's bullet No. 2, you state that "The filter caudally migrated 3 centimeters, tilted 18 to 20 degrees with the tip to the wall, 8 of 12 struts perforated, many to adjacent organs, vessels or structures, and three struts fractured." Right?
A That's correct.
Q What did you do to determine that Ms. Booker's filter experienced those things?
A I read the reports of Dr. Hurst and Dr. Muehrcke, and I also looked through medical records myself, although I primarily relied on

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Dr. Hurst and Dr. Muehrcke, although my reading of the medical records is consistent with what I saw in the reports by Dr. Hurst and Dr. Muehrcke.
Q So based on the medical records that you read, you can say that somebody other than Hurst and Muehrcke has said the filter caudally migrated 3 centimeters --
A Oh, sorry, I should -- so what I was able to determine is that some of these failure modes --
Q Okay.
A -- occurred.
Q But not with tiny detail?
A Not -- not with this detail.
Q Okay.
A And not all of them from the medical records. The others were gathered from the medical expert reports.
Q And you've said many times today you're not a doctor. You don't deem yourself to be qualified to read medical records and interpret whether what the doctor reported is accurate?
MR. O'CONNOR: Form.
THE WITNESS: That's correct.
BY MS. DALY:
Q And you do not deem yourself to be

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qualified to read imaging to a level that would allow you to determine the depth of a perforation or the amount of tilt, that kind of thing?
A I didn't read imaging in the -- in four of these cases, so -- and I don't -- I don't claim to be an expert in reading such imaging.
Q Okay. Muehrcke's report, if you want to look at that, at page 8, the top paragraph, and I hope I gave you ones that have page numbers on it because he didn't number his. Do yours have page numbers?
A No.
Q Shoot.
A So when I get to 8, it's the second to last page, is that --
Q Yeah. Sorry. At the top he says "There are multiple legs penetrating through the IVC wall," and then he describes "a leg extending into the aorta 8 millimeter" --
A Could you tell me which paragraph we're on.
Q Yeah, I'm at the very top here.
A That looks different from my copy so --
Q Hmmm.
A It's --

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Q Let me see your -- oh, right here. The first word there. "Multiple legs penetrating" --
A Okay. Start from there?
Q Yes.
A All right.
Q "Multiple legs penetrating through the IVC wall, with one extending into the aorta 8 millimeters." All right. That's the kind of information that you had to accept as accurate from Dr. Muehrcke?
A That's correct.
Q All right. How about the fact of tilt or caudal migration, is that something you were able to determine yourself?
A I did not determine that myself, and I don't recall whether I saw reference to tilt in the medical records.
Q All right. And then he goes on and says "Additionally, filter struts perforated the small bowel, psoas muscle, lumber vein at L4." Again, that's not something that you determined on your own?
A No, not by myself.
Q All right. And then Hurst's report, page 5 and 6, let's look at him.

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A Oh, Hurst. Sorry.
Q He put page numbers on there, which is good. And he starts with, like paragraph little C, he's talking about the -- the filter having no tilt and its placement -- no tilt, no fracture, and its placement at the right pedicle of the L2?
A Yes.
Q All right. This is not imaging you looked at yourself and made your own conclusions?
A No, I did not look at the imaging.
Q All right. And then he goes on in E and G on the next page and he gives very specific interpretations of the imaging, degrees of tilt, which arms at which position are in a Grade III or Grade II. You see those kinds of things?
A Yes, I see that, yes.
Q All right. And again, you would rely on Dr. Hurst for that?
A That --
Q For that kind of detail?
A Yes, that kind of detail, yes.
Q Okay. Do you know what he means by a Grade II or a Grade III perforation --
A I'd have to --
Q -- what his --

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A I'd have to look back at papers to find the definition of Grade III, but I have come across it in papers but I can't quote it to you.
Q Have you ever talked to him about what his definition is of Grade II --
A No, I have not.
Q -- or Grade III?
A No.
Q Okay. All right. Whoops.
And it appears that Dr. Muehrcke did not read imaging as -- in as much detail as Dr. Hurst; would you agree with that?
A I don't have any opinion on that.
MR. O'CONNOR: Form.
BY MS. DALY:
Q Okay. You don't know if they're consistent in what they've read or they're inconsistent?
A I don't know.
Q Okay. Dr. Hurst and Dr. Muehrcke both say in their reports, and you could look at Dr. Hurst's opinions in -- at paragraph 4, which is on page 8, and go to page -- I'm sorry -- I'm sorry, go to page 12. Under his opinions, page 12, H. Hurst says "In rendering my opinions in this matter, I

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took into consideration Ms. Booker's comorbidities, medical history and preexisting problems."
Do you see that he says that?
A I see that he says that.
Q And then Muehrcke on the last page of his report in Booker, just before his signature page, paragraph second from the bottom, he says exactly the same thing. "I was" -- "I am aware of Ms. Booker's comorbidities, medical history and preexisting problems, and these are taken into consideration in rendering my opinions."
Do you see he says that?
A The meaning of the sentence is the same, yes.
Q Okay. What comorbidities, medical history or conditions did they take into consideration as far as you know?
MR. O'CONNOR: Form.
THE WITNESS: Well, I don't know except what's in this report, so I'd have to read it and then identify what other problems the patient had, but I -- I'm --
BY MS. DALY:
Q And that really wasn't a good question. I'm sorry.

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Do you know what conclusions they drew from taking into consideration these comorbidities, medical history, and so on?
A No, I don't.
MR. O'CONNOR: Object to the form.
BY MS. DALY:
Q Okay. Did you take into consideration any of Ms. Booker's comorbidities, medical history or preexisting conditions?
A No, I didn't.
Q Do you know if she had any medical history, comorbidities, preexisting conditions that may have impacted the performance of her filter in any way?
A I -- I'm not aware of any. I -- I just don't know. I haven't gotten the information.
Q Did you read the deposition of the retrieving doctor in Ms. Booker's case, who is Dr. Kang?
A No, I did not.
Q Did he verify whether there was caudal migration?
MR. O'CONNOR: Form.
BY MS. DALY:
Q Do you know?

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A I don't know. Unless it's in the -- Dr. Hurst's or Dr. Muehrcke's report, which I'd have to read to find out, but otherwise I wouldn't know.
Q Okay. Whatever Dr. Kang had to say you did not rely on in giving this Booker report; is that fair?
A No, I did not.
Q Okay. Did you read any of the Bard case-specific medical experts' reports in the Booker case?
A No.
Q You conclude that the events that occurred to Ms. Booker's filter are consistent with the kinds of failures that you've discussed in your reports and we've discussed today, right?
A That's correct.
Q And, therefore, with respect to any tilt or any perforation or fracture or migration that might occur in a Bard filter, you're of the opinion that they were caused by filter defects?
A That's my opinion in that the -- their design and the testing of them was insufficient to reveal whether they were adequate to the task that they were expected to perform in the patient.

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Q Okay.
A And, therefore, that in -- in that sense, these filters are dangerous to the -- to the patient.
Q And -- and by "dangerous," again, you're not saying that from a medical standpoint, correct, whether when something happens to the filter it hurts them?
A That's correct, I'm simply observing that -- that these events, especially the fracture of a filter, seem like, or they are, undesirable phenomena that I would not like to have happen inside me.
Q You have not attempted to model or do any calculations with respect to Ms. Booker's vena cava size?
A No.
Q Her respiratory rate?
A No.
Q Her Valsalva experience?
A No.
Q Her -- the quality of her vena cava tissue or the quality, flexibility, inflexibility, of nearby organs?
MR. O'CONNOR: Object to the form of the

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question.
THE WITNESS: I haven't looked into that in any manner, although I should say that in my assessment, these failures are entirely predictable in the sense that they're going to occur in -- in some patients and they're going to be some -- they are going to be phenomena that will occur in some cases.
BY MS. DALY:
Q But that doesn't make it predictable because it happens in some cases and it doesn't happen in other cases?
MR. O'CONNOR: Form.
THE WITNESS: Well, it's predictable in a cohort of patients but not -- doesn't -- I'm not saying it's predictable in any specific case.
BY MS. DALY:
Q Are you saying it's predictable in any particular population of patients?
MR. O'CONNOR: Form.
THE WITNESS: I'm -- no, I'm not saying that. I'm saying that overall the individuals who receive filters, that it's predictable that some of them will fail in the manner that's observed in these cases.

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BY MS. DALY:
Q And you know that Bard warns in its IFU that those are risks associated with these filters, true?
MR. O'CONNOR: Form. Foundation.
THE WITNESS: I know that they warn of risks. I'm not completely familiar with -- with what risks they warn of.
BY MS. DALY:
Q And going back to my question, you also have not attempted to do any calculations specific to Ms. Booker putting in as variables which of her filter struts were perforating or the extent to which they were perforating, correct?
A Correct.
Q You have also not done any calculations in her case putting in this alleged caudal migration and what the extent of that caudal migration was, correct?
A Correct, I have not put that into any calculation.
MR. O'CONNOR: Object to form.
BY MS. DALY:
Q Nor have you put in any calculation on the degree of tilt that Dr. Hurst is reporting,

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correct?
A No, I have not done that.
Q So you have not generated any modeling specific to Ms. Booker that you can tell us "Here were the strains that were going on specifically in Ms. Booker in these locations at these times during the time her filter was in situ"?
A No, I haven't.
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: I have not done that.
BY MS. DALY:
Q All right. Let's talk about Ms. Hyde. All right. In Ms. Hyde's report, it's page 1 at the very bottom, the beginning of the last sentence to the top of page 2. You say the same thing you said in Ms. Booker's case, you say "I've determined to a reasonable degree of engineering and scientific certainty" -- "certainty that Ms. Hyde's G2/G2X filter experienced all the failure modes consistent with defects inherent in that filter," correct?
A That's correct.
Q Why do you say G2/G2X there as opposed to knowing if it's one or the other?

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A Because the information that I had didn't allow me to tell whether it was actually a G2 or a G2X filter that was involved.
Q Okay. Then in your report page 1, bullet 2, you note that Mrs. Hyde's filter tilted, caudally migrated, perforated in multiple struts, and an arm fractured and embolized to her heart, right?
A Correct.
Q When you say "arm," do you mean arm or do you mean a strut?
A I mean a strut.
Q So it could have been an arm or a leg?
A Could have been an arm or a leg.
Q You don't know which?
A Correct.
Q All right. Do you know -- what did you do to determine if Ms. Hyde experienced these events or when?
A I read the reports by Dr. Hurst and Dr. Muehrcke.
Q Okay.
A And I read her medical rec- -- the medical records I had available to me, and the combination of those sources gave me the information, which is

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in these bullet points.
Q Did you principally rely on what either Dr. Muehrcke or Dr. Hurst said?
A I principally relied on them.
Q Okay. So let's look at Muehrcke first, and his report on page 1, paragraph 1, lists as her failure modes there before the colon, "Caudal migration, tilt fracture, perforation, penetration of adjacent organs and structures, and embolization of a fracture of the filter that fractured."
Do you see that?
A I see that, yes.
Q Then Dr. Hurst -- oh, and he doesn't -- I note that Dr. Muehrcke doesn't cite to any medical records where he got that information. I mean, he lists medical records he saw but I mean right where he's talking about those things, he doesn't cite to a -- to a medical record, correct?
A Yeah, there's no citation right there. I'd have to review the whole report to see whether he cites specific records elsewhere.
Q He -- he lists -- well, I thought he listed records but I don't see them. At any rate, let's go to Hurst. Page 6.
A Okay.

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Q Paragraph 4, little 2.
A Okay.
Q Hurst says that the filter was implanted, that's little 1, was implanted on 2-25-11, and then little 2I he says "Filter subsequently caudally migrated, with penetration of multiple arms and legs, ultimately led to fracture of a stabilizing arm that went to the right ventricle."
Do you know whether in her case the fracture was an arm or a leg?
A Well, reading this section, I assumed it's an arm because of how that paragraph was written.
Q Do you know for sure?
A I don't know for sure.
Q Okay.
A Since often, as I think you probably know, there are different terms used for different struts.
Q Right. Some people call all the pieces struts, some call them arms.
A Right.
Q Okay. Now, in this report on Ms. Hyde, different from the report that Dr. Hurst did on Booker, if you look through here with me there is not a detailed interpretation by him of imaging

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where he says, you know, the 1:00 arm is doing this, the 6:00 arm is doing that?
MR. O'CONNOR: Object to the form of the question.
BY MS. DALY:
Q Correct?
A Well, sorry, can you draw me -- draw my attention to --
Q Yeah. I don't see where he said that anywhere.
A Well, again, I'd have to look through the whole report to confirm that but --
Q Well, he doesn't.
A Yeah.
Q And you're welcome to look through that, but you'll see he doesn't with the specificity he did for Booker. He doesn't say which -- which filter strut is perforating to what degree on what image. That's my only point.
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: That would appear to be the case.
BY MS. DALY:
Q Okay. So what we don't have from

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Dr. Hurst -- and you're welcome to look at Dr. Muehrcke's too, he doesn't do it either -- what we don't have from Muehrcke or Hurst is any detail of information about which struts perforated, how much they perforated or when they perforated relative to each other or relative to the fracture?

MR. O'CONNOR: Form.

BY MS. DALY:

Q Is that fair?

MR. O'CONNOR: And foundation.

THE WITNESS: That would appear to be the case.

BY MS. DALY:

Q Okay. Now, with respect to Ms. Hyde, do you have any information on your own or from Dr. Hurst or Dr. Muehrcke about what her vena cava tissue quality, firmness, flexibility was?

A I have no information on that.

Q Or what her blood flow was?

A No, no information on that.

Q What her respiration rate was?

A I have no information on that.

Q What her experiences were with Valsalva?

A No information on that.

Q Do you know how the sleep apnea that she's

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been diagnosed with may have impacted her filter?

A No, I haven't thought about that.

Q Okay. What about her smoking history, how that might have impacted the filter?

MR. O'CONNOR: Form. Foundation.

THE WITNESS: I'm not an expert in medicine, so I'm not able to make that to -- assessment.

BY MS. DALY:

Q And another one is did you -- did you try to determine how, if at all, anti-coagulant use might have impacted issues with the filter?

A No, I haven't made that assessment since I'm not an expert in -- in that aspect of the situation.

Q And Drs. Hurst or Muehrcke, or any other doctor for that matter, did not give you any such information for -- for Ms. Hyde?

A I didn't observe anything about that.

Q All right.

A At least I don't recall observing anything like that in their reports.

Q Once again in the same areas in their report, Hurst and Muehrcke both say we took into consideration the plaintiff's comorbidities,

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medical history and preexisting conditions. Same question I had for you for Ms. Booker and Ms. Hyde: You don't know what Dr. -- what Dr. Hurst or Dr. Muehrcke took into consideration about those items?

A No, I don't know how -- what they took into consideration.

Q Okay. And you did not take those things into consideration in your opinions?

A No, I did not.

Q Okay. Do you know that it's Dr. Kuo that removed Ms. Hyde's filter and strut?

A I don't recall whether I read that somewhere but I may well have, but...

Q Do you know whether he reported that there was caudal migration or not?

A I read the medical records and that may have been in there, but I don't recall whether it was.

Q Was there anything that he provided, as far as you recall, about when any migration of her filter, if it happened, began and what its progression was over time?

A No, I don't recall that. It -- it may have been in the medical records I read, but I

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don't recall the details.

Q Did you take any details from Dr. Kuo's operative report or his deposition about what he observed with respect to perforation of any of the struts of the filter when he went to retrieve it?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: I didn't use any of that information.

BY MS. DALY:

Q And likewise, did you use any information from Dr. Kuo about whether any of the struts were perforating into any adjacent organs, vessels or anything like that?

A No, I didn't take any of that information or use it.

Q And -- and you didn't have any information about what the quality of tissue or the density of tissue was in any of her adjacent organs or vessels?

A No, I didn't have any information about that.

Q In your report on Hyde, your own report, in -- on page 1, bullet 3, you say that she underwent successful retrieval of the filter and a

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complex procedure performed by Dr. Kuo of the filter fragment from the heart.
A Yes.
Q Do you know what "complex procedure" means?
A Well, again, since I'm not a medical expert I don't know precisely what it meant, but since the -- since the fragment was in the heart, it must have been a complicated procedure that was undertaken.
Q I guess my -- did you borrow that term from some medical thing that you read as opposed to your own opinion that it was complex?
MR. O'CONNOR: Form.
THE WITNESS: It was my interpretation of what I read in the Hurst and Muehrcke reports and possibly also what I read in the medical records from Dr. Kuo's reports.
BY MS. DALY:
Q Did you read what Dr. Kuo's procedure notes indicated that the procedure entailed, the procedure that he did entailed?
A I believe I did read it, but I don't recall any details.
Q Do you recall that he described for the

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strut retrieval that it was a single snare attempt of the filter and immediate removal of the strut?
A I don't recall that.
MR. O'CONNOR: Form.
BY MS. DALY:
Q Okay. Would you defer to medical people to describe how complex or difficult this procedure was for Ms. Hyde?
A Well --
MR. O'CONNOR: Form.
THE WITNESS: -- going with a catheter inside the heart and with a snare seems like a complex procedure to me, but I would defer to medical experts in terms of where that scales on the level of complexity.
BY MS. DALY:
Q Okay. In your report on page 1, bullet 4, you state that in Ms. Hyde's case the filter was "used as intended, properly implanted and there were no other causes for failure," so I want to talk about those one at a time. Okay?
A Okay.
Q What do you mean with respect to Ms. Hyde's case that the filter was used as intended?

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A Well, it was implanted as a filter in her vena cava.
Q Okay.
A And it -- I rely on Dr. Hurst and Dr. Muehrcke for that information.
Q And did you know that in her case she'd had recurrent DVT and pulmonary embolus in the past?
A I may have read that in her medical records but I don't recall.
Q And you're not -- when you say the filter was used as intended, you're not intending to make any comment about whether she was a proper candidate for the filter medically?
A No. No.
MR. O'CONNOR: Form.
BY MS. DALY:
Q Okay. You said that the filter was properly implanted. On what information do you rely for that?
A Well, I rely on Dr. Hurst and Dr. Muehrcke who -- who, as I recall, state that the implantation was successful.
Q Okay. You've made no independent assessment of that?

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A No.
Q Okay. The next thing you said is that no other causes of the failures of that filter -- that there were no other causes of the -- yeah, there were no other causes of the failures of that filter. What does that mean, first of all?
A Well, the -- I -- it means that the experiences that I've described that implanted filters go through when they're implanted in the vena cava, such as expansion and contraction of the wall of the vena cava and blood clots hitting it and the other things that we've talked about, were the causes of the failure of the filter.
Q But do you agree with me that you did not investigate anything specific about Ms. Hyde's anatomy?
A No, I didn't investigate that.
Q Or her medical conditions?
A No.
Q Medical history?
A I did not review other than the medical records that were related to the filter.
Q You just noted that for medical records or from what Hurst and Muehrcke said, there was a tilt, perforation, fracture and/or migration in her

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filter?
A Correct.
Q Okay. Now, do you understand that nobody has had the opportunity to examine either the retrieved filter or the retrieved piece of Mrs. Hyde's filter?
A I need to look --
MR. O'CONNOR: Form.
THE WITNESS: -- at my report to see what it -- what I obtained from the information.
Well, I don't comment on that, so I don't know where the filter is and where the fragment is.
BY MS. DALY:
Q Okay. You have not seen any report from Dr. Richie, for example, or Dr. Fasching examining that filter?
A No.
Q So what we don't have as a piece of this puzzle is whatever that filter or fragment might have shown us that would give us any information about the fracture, correct?
MR. O'CONNOR: Form.
THE WITNESS: Well, I don't know whether Dr. Fasching or Dr. Richie have inspected the filter, but if they haven't inspected the filter,

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then we don't have such information unless someone else has inspected it for anyone in the -- in the case.
BY MS. DALY:
Q All right. Okay. Then you concluded that -- in your report that the events that occurred with Ms. Hyde's filter were consistent with the kind of failures that you have discussed in your prior reports and in -- and in this deposition with me today, right?
A Correct.
Q Okay.
A So they're -- they're consistent and they support my assessment of those -- of those failure modes.
Q Well, they're consistent with what you -- with the modes you've talked about, correct?
A Correct.
Q All right. But you have done no modeling or calculations specific to anything about Ms. Hyde, including you didn't calculate her vena cava size, respiratory rate, Valsalva experience, any other medical condition she had, extent of her perforations, distance of her caudal migration, degree of any tilt, extent to which the filter was

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catching clots, for example, to calculate any -- what strains were on her filter or any portion of her filter at any time it was in situ, true?
MR. O'CONNOR: Form.
THE WITNESS: True, I have done none of that.
BY MS. DALY:
Q Okay. All right. Let's talk about Ms. Jones. As with the previous two Bellwether reports, on page 1 -- actually, I'm sorry, it's at page 2 at the top of the page -- you say again, "I've determined to a reasonable degree of engineering and scientific certainty that Ms. Jones' Eclipse filter experienced all the failure modes consistent with defects inherent to that filter," correct?
A Yes, that's what is written, yes.
Q And then on page 1, bullet 4 of your report, you list complications for Ms. Jones as filter tilt, migration, and one strut fractured, correct?
A Let me read through the information.
Yes, they're all there, yes.
Q And then you note that the in situ fragment is in her right pulmonary artery?

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A Yeah, at the time that I wrote this report, that was the information available to me.
Q Do you know anything new now?
A I don't know anything else --
Q Okay.
A -- since then.
Q So once again, as you said with the last ones, you principally relied on Dr. Hurst and Dr. Muehrcke's report of what was happening with this patient, correct?
A That's correct.
Q All right. So Dr. Muehrcke on page 1 of his report, it's about the fourth line down, he says the Eclipse filter implanted in her had the following failure modes, and he has caudal migration, tilt and fracture of the filter, with embolization to the pulmonary vascu- -- vasculature. Do you see that?
A I see that, yes.
Q Okay. And again, he does not -- you can flip through -- he does not discuss in any detail at all where he gets that information.
MR. O'CONNOR: Object.
BY MS. DALY:
Q He's listed some medical records at page

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6, which is four -- yeah, page 6 in.
MR. O'CONNOR: I object to the form of the question.
THE WITNESS: Sorry, is that a question?
BY MS. DALY:
Q Yeah.
A What's the question?
Q The question is: Do you see anywhere that he has cited to a particular medical record that shows these failure modes that he's listed on page 1?
A Well, not a specific citation, but he -- I think it's the same page that you're referring to. He says "I also reviewed the following case-specific medical records and images."
Q Correct. But which of those show which failure mode, he hasn't expressed that, correct?
MR. O'CONNOR: Form.
THE WITNESS: I need to read through them all to see what's said against each of them.
Well, there's one that says "Chest X ray with IVC filter being at the L2 lower vertebral body and vertical, mostly with 4 percent tilt to the left."
BY MS. DALY:

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Q Right, so on page -- on page 7 he's got a bullet point that says that, correct?
A Well, I don't know if -- I have to count to get --
Q I know.
A -- to whether it's page 7.
Q Sorry about that.
A But it's -- it's just above a section that's entitled "Case-specific" --
Q Correct.
A -- "opinions regarding Doris Jones."
Q Correct.
A And then there's IV- -- there's -- it doesn't say what it is but he does refer specifically in the next line to "IVC filter with a right mid-lung metallic object near the right hilum," and then --
Q Uh-huh.
A -- the next one down referring to PA and lateral films which show the right middle lung metallic device.
Q Okay.
A So there are some -- there's some specificity.
Q Okay. And what he has here for amount of

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tilt, the only thing I see is the 4 percent, which I'm not sure what that means, we normally -- you and I normally talk about that in degrees, right?
A Correct. Yeah.
Q All right. So then let's look at --
MR. O'CONNOR: Belated objection to the form.
BY MS. DALY:
Q -- Dr. Hurst.
A Can I comment that you can -- you could compare it to degrees.
Q Okay. Degrees or percent?
A Degrees or percent, they are more or less equivalent.
Q Well, wait a minute. Degrees goes around in a circle and that's 360, and percent only has 100. I'm a lawyer.
A Right.
Q Yeah, we won't -- we won't waste time on that.
A Sorry, I was thinking of radians, radians, which you then have to convert.
Q I will not put my math up to yours.
A You're -- I stand corrected. I stand corrected.

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Q That was pretty smart of me just then.
Okay. Hurst, let's look at Hurst, page 5, and if you look under B he's talking about the implant or Dr. Avino positioning it, the filter in her case, with the superior tip at L2-L3. Do you see that?
A Yes.
Q All right. And then below that, on E, he also talks about the filter fragment in the right middle lobe of the pulmonary artery?
A Yes.
Q Okay. All right. Okay. Beyond what's in Dr. Hurst and Dr. Muehrcke's reports, did you do anything else to verify whether there were perforations, for example, in the case of Ms. Jones?
MR. O'CONNOR: Form.
THE WITNESS: Well, I read some medical records but I didn't directly look at them to -- well, I did, I looked for whether they mentioned things like something outside of the vena cava, but I didn't -- I didn't correlate what was -- what I saw with what was in the Muehrcke and Hurst reports.
BY MS. DALY:

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Q So do you know if she had perforations or not?
A I don't know.
Q Okay.
A Actually, I should look at this again to see what it says in the summary.
Q Sure.
A So there's no mention of perforations, so it appears that there's no record of perforation.
Q All right. And you read off a moment ago that in Dr. Muehrcke's report he shows the tilt of 4 percent or 4 degrees, whatever --
A 4 percent.
Q He says percent. Okay.
Do you know -- well, I'm assuming you haven't talked to Dr. Muehrcke about what he means by 4 percent?
A No, I haven't.
Q Whether it's our 4 degrees or it's something else?
A No, I haven't talked to him.
Q Okay. Do you know that physicians who use IVC filters typically don't consider a tilt to an IVC filter to be clinically significant unless it's 15 degrees or above?

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MR. O'CONNOR: Form.
THE WITNESS: I don't know that for a fact myself.
BY MS. DALY:
Q Okay. And then again, other than Muehrcke's information about a 4 percent tilt, do you have any other information of her filter progressing beyond that to a greater degree of tilt at any time that she had it?
A Not to my recollection.
Q And again with her, you have not gotten any information that gives you data on what the quality of her vena cava tissue is or its firmness or its flexibility?
A No.
MR. O'CONNOR: Form.
BY MS. DALY:
Q And you have not had any information about what her blood flow was?
A No.
Q Her respiratory rate --
A No.
Q -- while she had the filter?
A No.
Q What information -- any information about whether she experienced Valsalva movements?

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MR. O'CONNOR: Form.
THE WITNESS: I have no information about that.
BY MS. DALY:
Q Do you know how her history of GI bleeds and being on anti-coagulants may have impacted the filter?
A Since I'm not a medical expert, I have no view on that.
Q Okay. And once again in this report, Dr. Hurst and Dr. Muehrcke both say they took into consideration the plaintiff's comorbidities, medical history and preexisting conditions with respect to her. Do you know what interpretation, if any, they made of those things?
A No.
MR. O'CONNOR: Object to form.
THE WITNESS: I don't know.
BY MS. DALY:
Q And you did not take those into consideration yourself in drawing your conclusions?
MR. O'CONNOR: Objection. Form.
THE WITNESS: No, I did not.
BY MS. DALY:

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Q Okay. Now, in Mrs. Jones' case, did you read the deposition of her retrieving doctor, a Dr. Kristin Nelson?
A No, I did not.
Q Do you know if she verified whether there was migration of the filter?
MR. O'CONNOR: Form.
THE WITNESS: No, I don't -- I don't know that.
BY MS. DALY:
Q Or perforation?
A I don't know. I don't know.
Q Okay.
A I don't know what she said.
Q Okay. About any complication --
A About anything.
Q -- that she saw?
A Yeah, about anything.
Q You do know that she saw a fracture because she made an attempt to remove the piece?
A Well, I may have observed that in the medical records, but I don't recall exactly whether it was this case or another one.
Q Okay.
A Of course it may have been someone else,

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another physician involved if it was another case.
Q All right. Now, also in Mrs. Jones' report on page 1 at your bullet -- your last bullet there, bullet 5, you say that "Ms. Jones' Eclipse filter was used as intended, properly implanted, and there was no other causes of failures of that filter."
Again with her, what did you mean for her when you said the filter was used as intended?
A I mean it was implanted in her vena cava and it functioned as a filter within her vena cava.
Q And you didn't try to make any assessment whether her previous bleeding issues or anything made her a good candidate for the filter?
A I did not make that assessment.
Q Okay. Did you make any assessment of whether it was properly implanted or you just accepted the doctor's statements on that?
A I relied on --
MR. O'CONNOR: Object to form.
THE WITNESS: -- Dr. Hurst and Dr. Muehrcke in -- on that question.
BY MS. DALY:
Q And then with respect to your comment "no other causes of failures of the filter were

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present," you did not, in making that -- in giving that opinion, you did not investigate anything specific to Ms. Jones' anatomy or medical conditions, medical history, true?
A Correct.
MR. O'CONNOR: Form.
BY MS. DALY:
Q And in her case, has -- do you -- nobody has sent you a report showing that they have examined the removed filter, correct?
A That's correct.
Q And assuming that the piece is in situ and we don't have the filter, we can't look on either the filter or the piece to determine what it might tell us about cause of fracture or contribution to -- to the fracture, correct?
MR. O'CONNOR: Object to the form.
THE WITNESS: I need to look at what I say.
So I don't know where the filter is. It was removed successfully, but otherwise I don't know where it is. And as of the time of writing of this document, the fragment was still within her, so...
BY MS. DALY:

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Q So without those pieces of evidence, we -- we don't have the physical evidence from the fragment or the filter to help us look at causes of the fracture, true?
MR. O'CONNOR: Form.
THE WITNESS: Without either the filter or the fragment, that information's not available. Or cannot be obtained safely.
BY MS. DALY:
Q So again in your report, you concluded that events that occurred with Ms. Jones' filter were consistent with the kinds of failures that you've discussed in your prior reports and in this deposition today, correct?
A That's correct.
Q Okay. And again, you have not attempted to do any modeling or calculations specific to Ms. Jones that might include consideration of her vena cava size, respiratory rate, Valsalva experience, vena cava or surrounding organ tissue quality or stiffness, existence or extent of perforations, existence of or distance of any alleged caudal migration, the degree of tilt of her filter, whether the filter was catching clots at the time, in order to calculate any strains that

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might have been occurring in her filter at any location at any time, true?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: I have not done any calculations related to those phenomena that you describe.
BY MS. DALY:
Q So we'll go to --
MR. O'CONNOR: What is the time, by the way?
BY MS. DALY:
Q -- Ms. Kruse.
THE VIDEOGRAPHER: It's 4:12.
MR. O'CONNOR: No, how long have we been on?
THE VIDEOGRAPHER: We've been on the record for 5 hours and 36 minutes.
MR. O'CONNOR: Thanks.
BY MS. DALY:
Q And just -- you don't have to go off the record for this, the reason I'm going through each one of these boringly repetitively is that they'll each be separate cases, obviously, so I want to do each one separately.

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A Thank you for clarifying that. Thank you.
Q It's not that I'm just done and I'm water hammering you.
Okay. So we're going to Ms. Kruse. In your report on Ms. Kruse on page 1, in the bottom paragraph you say "I determined to a reasonable degree of engineering and scientific certainty that Ms. Kruse's G2 filter experienced all of the failure modes consistent with defects inherent in that filter," correct?
A That's correct.
Q And then on page 1 at bullet 3 you talk about the failure modes, and you've listed filter tilted in excess of 15 degrees and embedded in the wall; 5 of 12 struts of her IVC filter perforated the vena cava with involvement of vital organs, vessels and structures; filter caudally migrated approximately 5 centimeters; and filter not retrieved and remains in place.
A That's correct.
Q All right. And what did you do to determine that Ms. Kruse's filter had experienced each of those events?
A I read the medical records that I had available to me, I read Dr. Hurst's report and

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Dr. Muehrcke's report.
Q Okay. And would -- do you rely on Dr. Hurst and Dr. Muehrcke's report principally for being able to say that her filter experienced these things?
A Yes, I relied principally on those two reports.
Q All right. Let's look at Hurst on her first. Page 5. Section D. If you would, go back a page to page 4 and look at -- under "Case Summary," paragraph 3A and B. Dr. Hurst is reporting that a G2 filter was placed on July 8, 2009 in Ms. Kruse, correct?
A Yes, the date against that paragraph is the 8th of July 2009.
Q Yes. And then if you look at his comments in D where he is referencing a CT of abdomen and pelvis 3-7-11 --
A Yes.
Q -- he is commenting on "The tip of filter caudally migrated 5 centimeters."
A Yes.
Q So at least based on Dr. Hurst's materials, somewhere between implant in July of '09 and this CT in March of '11 the filter caudally

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migrated?
A That's correct.
Q Okay.
A According to this information.
Q And then below that he says that the filter is tilted more than 15 degrees --
A Correct.
Q -- do you see that?
A Yes.
Q And he identifies perforation with a vertebral body and an iliac artery wall of some struts there?
A Which -- which line is that?
Q In little -- in Roman vi, vii, viii, ix and x, he's talking about different perforating struts.
A Yes.
Q And he also gives his grading, II or III on that, right?
A That's correct.
Q And you do not know what Dr. Hurst's own definition is of Grade II or III?
A No, I don't.
Q Okay. Do you have any information that Ms. Kruse's filter has tilted more than the amount

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that Dr. Hurst is commenting on it in this imaging in 2011?
A Well, I would have to read through the report to see whether that's mentioned elsewhere in the report --
Q Okay. Go ahead.
A -- and in Dr. Hurst's report and I -- possibly read the medical records again, but right as I -- what I have now, I don't have information about that.
Q Okay.
MR. O'CONNOR: Well --
BY MS. DALY:
Q And do you have any information about any changes in the number or extent of perforation of struts in her filter as described by Dr. Hurst here?
A Well, I really should read what's in here before I --
Q Yeah, go ahead.
A -- answer the question.
Q Go ahead.
MR. O'CONNOR: Let's take five minutes while he's doing that, please.
MS. DALY: Uh-huh.

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THE VIDEOGRAPHER: We're going off the record at 1617.
(Brief pause.)
THE VIDEOGRAPHER: We're back on the record at 1618. This is the end of Media No. 4. We are going off the record at 1618.
(Recess taken.)
(Whereupon, Deposition Exhibits 7A, 7B, 8A, 8B, 9A, 9B, 10A, 10B, 11A and 11B were marked for identification by the Court Reporter.)
(Record read as follows:
"And do you have any information about any changes in the number or extent of perforation of struts in her filter as described by Dr. Hurst here.")
THE VIDEOGRAPHER: This is the beginning of Media No. 5. We are back on the record at 1625.
THE WITNESS: Well, having read the report, I realize that Dr. Hurst says that it was observed that the filter tilted to more than 15 degrees at some stage.
So correcting what I said before, there is information that says that the tilting preceded

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beyond 15 degrees. I have -- the comment on perforation is -- is not there to allow me to -- sorry, there is no comment on the perforation in a manner that allows me to say whether perforation increased in number in terms of the number of limbs involved or progressed further than it was in the observation at the 7th of March 2011.
BY MS. DALY:
Q All right. Let's look at Dr. Muehrcke, page 1. In that first paragraph he describes the following failure modes: Caudal migration, tilt, fracture, perforation of the vena cava, penetration of adjacent organs and structures, and irretrievability.
MR. O'CONNOR: Where -- where are you looking at? I'm sorry.
MS. DALY: Page 1 of Muehrcke. We're not in Hurst, we're on Muehrcke.
MR. O'CONNOR: Are you talking about Kruse?
MS. DALY: Yeah.
MR. O'CONNOR: Okay. Thank you.
BY MS. DALY:
Q Do you see where he's said that?
A Oh. Yes. Yes.

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Q Okay. Do you have any information either on your own or from Dr. Hurps -- Hurst or anything that Dr. Muehrcke cites to that Ms. Kruse has a fracture?
A I need to look again at my report.
Q Sure.
A See what I say.
I make no mention of fracture, so that would indicate that there is no information indicating a fracture has taken place.
Q Okay. And with Ms. Kruse, you have not received any information about the quality, flexibility, firmness, or lack thereof, of her vena cava tissue?
A Correct.
Q Or of the stiffness, lack of stiffness, or makeup of her vertebral bodies or iliac artery vessel?
MR. O'CONNOR: Form.
THE WITNESS: No specific information on that.
BY MS. DALY:
Q You don't have any information about what her blood flow was?
A No information on that.

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MR. O'CONNOR: Form.
BY MS. DALY:
Q Or what her typical respiratory rate was?
A I have no information on that.
Q Do you have any information on whether she experienced Valsalva movements and to what extent?
A I have no information on that.
Q Do you know whether her diabetes, anemia, use of anti-coagulants or her cancer issues played any role in impacting the filter?
A Since I'm not a medical expert, I can't make an assessment of that.
Q Dr. Hurst and Dr. Muehrcke in this report also said they took into consideration the plaintiff's comorbidities, medical history and preexisting conditions. Again, you do not know what interpretation of those they did; is that correct?
A That's correct, I don't know what interpretation they placed on that.
Q And you did not interpret or rely on anything about her comorbidities, medical history or preexisting conditions in your opinions, true?
A That's correct.
Q On page 1 of your report, and it's bullet

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4, you -- you say that her "G2 filter was used as intended, properly implanted, and there were no other causes of failures of that filter."

With respect to Ms. Kruse, are you giving any opinion with respect to whether she was an appropriate candidate for the filter?

A I'm not giving any opinion on that.

MR. O'CONNOR: Form.

BY MS. DALY:

Q Are you aware that she had had recurrent DVT and PE with anti-coagulants prescribed before the time that she was implanted with the filter?

A I may have been aware of that from reading her medical records, but I don't recall.

Q With respect to the comment on "proper implant," would you defer to Dr. Hurst or Muehrcke or the medical records about whether that was a properly done implant?

A Well, I would defer to Drs. Hurst and Muehrcke and the physician who prepared the medical records.

Q Okay. With respect to your comment "no other causes of the failures of the filter," did you investigate anything specific to Ms. Hyde's anatomy or medical conditions?

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MR. O'CONNOR: Kruse.

MS. DALY: Oh. Sorry.

MR. O'CONNOR: That's all right.

BY MS. DALY:

Q Did you investigate anything specific to Ms. Kruse's anatomy, medical conditions, history or comorbidities?

A No, I did not.

Q If there was any fracture in this filter, you're not aware of anyone having been able to inspect the filter or the fractured limb, correct?

MR. O'CONNOR: Form.

THE WITNESS: Repeat the -- repeat the question, please.

BY MS. DALY:

Q Yeah.

You don't know if -- if anyone -- if there is a fracture in this filter, you are not aware of anyone who has looked at either the filter or the fragment, true?

A That's correct.

Q So to the extent -- to the extent that looking at the filter or the fragment might tell us something about causation of the fracture, as far as you know that has not been done?

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MR. O'CONNOR: Form.

THE WITNESS: That has not been done, so the information directly from the fracture surface has not been obtained. But, nevertheless, we still know to a reasonable degree of -- of engineering probability that if it has fractured as in -- that as in the other cases which have fractured, that the cause is very probably fatigue fracture.

BY MS. DALY:

Q But there are other causes that you all have talked about, Dr. Richie and you have talked about, that initiate fracture besides -- like perforation, right?

MR. O'CONNOR: Object to the form.

BY MS. DALY:

Q Let me restate that.

A I --

Q There are causes of fracture that might include contact wire to wire that you might be able to see on surfaces, true?

A But -- but that would initiate fatigue fracture.

Q Right. Well, everything -- to have a fatigue fracture, you've got to have fatigue, right?

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A Yes. Correct.

Q Okay. So in every case, if it is determined that a fracture was fatigued as opposed to a cutting -- a cutting of the wire or something like that, there's going to be some cause for fatigue, correct?

A Okay. The -- the statement I made is that it is a fatigue mechanism that causes the fracture, and that fatigue mechanism will go back to some source that initiates the fatigue cracking and the fatigue damage that the filter is experiencing, although filter -- although just cycling the material through a range of strains will cause fatigue damage within the material, so even if there are not features present in the material that you can identify specifically as associated with the design of the filter or its manufacturing.

So my point is simply that it is fatigue failure that is most likely to have caused the fractures that we're looking at in all of these cases, if there are fractures --

Q Okay.

A -- in any given case.

Q And you will agree with me that with respect to any given person, there are numerous

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permutations of conditions that the filter can be in?
A There are many configurations it can be in, yes.
Q And those can be impacted by patient-specific things?
A That's correct.
Q And they can be dependent on -- well, I'll just leave it at that, patient-dependent things, you agree with that?
MR. O'CONNOR: Form.
THE WITNESS: I agree, but these patient-dependent things are entirely predictable in terms of what will happen over a population of patients who are implanted with vena cava filters.
BY MS. DALY:
Q But what's not predictable is whether Ms. Kruse will have a perforation and Ms. Smith might not?
MR. O'CONNOR: Form.
THE WITNESS: Well, without the relevant information, that -- it's not possible to make that prediction.
BY MS. DALY:
Q Right. You can't ever predict for a given

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person what complication they're going to have with the medical device, true?
MR. O'CONNOR: Form.
THE WITNESS: Well, I think you can, but the -- gathering the information you need to do that is the challenge --
BY MS. DALY:
Q Yeah.
A -- rather than the actual carrying out of the prediction.
Q Okay. And now with respect to Ms. Kruse, I think this is where I was, you have not attempted to do any models or calculations specific to her as a patient, for example, using as a variable her vena cava size, her respiratory rate, any Valsalva experience she had, the quality of her vena cava tissue or surrounding organ or vessel tissue, the extent of her perforations, the degree of any tilt that she had, the extent to which the filter was catching clots, to calculate specific strains in any portion of the filter at any time in her?
A That's correct.
MR. O'CONNOR: Form.
BY MS. DALY:
Q All right. Let's talk about Ms. Mulkey.

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With Ms. Mulkey, your report at the top of page 2 says that "I have determined to a reasonable degree of engineering and scientific certainty that Ms. Mulkey's Eclipse filter experienced all the failure modes consistent with defects inherent in that filter," correct?
A That's correct.
Q And then your report page 1, bullet 3, says that her filter tilted approximately 20 degrees and embedded to the wall of the IVC, 4 of 12 struts of her IVC perforated the vena cava with involvement in vital organs and structures adjacent to the vena cava, her filter migrated approximately 3 centimeters, and one of the stabling arms of her filter fractured and has yet to be located.
On what information did you rely for those events?
A A combination of the medical records and in this case there -- I think I'm correct in saying there were some copies of imaging, so I need to look at that.
Q Okay.
A I think it's this case I had some images, copies of images, but I'm not absolutely sure. But I looked at that, I looked at the medical records,

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and I looked at the reports by Drs. Hurst and Muehrcke.
Q Were you able to confirm that there was any fracture?
A You mean -- can you repeat the question and clarify.
Q Yeah.
Were you able to confirm that there was a fracture in Ms. Mulkey's filter?
A You mean independently of reading the reports by Drs. Hurst and Muehrcke?
MR. O'CONNOR: Object to the form of the question.
BY MS. DALY:
Q Which of them indicates that they have identified a fracture?
A I need to look through those reports to --
Q Sure.
A -- determine that.
MR. O'CONNOR: Go ahead.
BY MS. DALY:
Q And let me help you. Are you on Hurst?
A I'm on Hurst, yes.
Q Look at page 6, G, F and G.
A Yes, it says in F that -- that the -- that

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it was demonstrated that there was additional failure to the filter with an internal fracture of the 11:00 stabilizing arm.
Q And what does Dr. Muehrcke say about fracture, other than on -- on page 1 he says that the failure modes were caudal migration, tilt, fracture, perforations of the vena cava and perforation --
A I would have to look at the report to see that.
Q Yeah. Okay.
A On the second to last page.
Q Uh-huh.
A In the first full paragraph it says, in the sentence that begins -- one, two, three, four, five, six, seven -- seventh line, "This risk of harm is ongoing as Ms. Mulkey is exposed to further and progressive perforation of her vena cava, penetration of adjacent vital organs and structures, additional strut fracture, and embolization of the existing fracture fragment." And then there's more words in that sentence, too.
Q Okay. Does he -- does he cite to where he's -- he's seeing this alleged strut fracture or progression of perforation?

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MR. O'CONNOR: Object to the form of the question.
THE WITNESS: He does not specifically cite any observation, but nevertheless, I find the report very informative because of the information which is within it.
BY MS. DALY:
Q If --
A As I do the report by Dr. Hurst and all the other reports in the Bellwether cases.
Q Have you read any of Bard's case-specific medical experts?
A No, I have not.
Q Do you know that the doctors don't agree about there being a fracture in Ms. Mulkey?
A I'm not aware of that.
MR. O'CONNOR: Object to the form of the question.
BY MS. DALY:
Q Do you know that the doctors don't agree about there being a fracture in Ms. Kruse?
MR. O'CONNOR: Object --
THE WITNESS: I'm not --
MR. O'CONNOR: -- to the form of the question.

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THE WITNESS: I'm not aware of that.
BY MS. DALY:
Q You noted in your report a foreign -- what did you say? The -- something about a foreign object that has yet to be located?
A Can you find the --
Q Yeah, let me --
A -- the line.
Q I think it's in your final bullet point there. Yeah.
A Final bullet point on page --
Q No, it's the third bullet point. The last line of the third bullet point.
A Oh. So it says "One of the stabilizing arms of her filter fractured and has yet to be located." Is that the --
Q Yeah.
A That's what you're referring to?
Q And -- and you're basing that on Hurst and Muehrcke's saying that there's been a fracture and it hasn't been located?
A That's correct.
Q Okay. I mean, I'm making -- you haven't looked at imaging and said "Oh, there's no fracture located"?

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A No, I haven't done that.
Q Okay. And with respect to Ms. Mulkey, do you have any information about her tissue quality, firmness, flexibility, or lack thereof, in the vena cava?
MR. O'CONNOR: Form.
THE WITNESS: No, I have no such information.
BY MS. DALY:
Q Do you have any information about her -- her tissue quality, flexibility, firmness, or lack thereof, in any of her adjacent organs or vessels?
A No, I have no specific information about that.
Q Did you have any information about what her blood flow rate was?
A No, I have no such information.
Q Or about her respiratory rate?
A I have no such information.
Q Or about information -- any information about her experience of Valsalva movements or how often?
A No, I have no such information.
Q Dr. Hurst and Dr. Muehrcke both said in their reports that they took into consideration

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plaintiff's comorbidities, medical history and preexisting conditions. Do you know what interpretation they have made of those items?
A No --
MR. O'CONNOR: Form.
THE WITNESS: -- I do not know.
BY MS. DALY:
Q And you have not taken into consideration any comorbidities, medical history or preexisting conditions in Ms. Mulkey in making your opinions in the case?
MR. O'CONNOR: Object --
THE WITNESS: No --
MR. O'CONNOR: -- to the form of the question.
THE WITNESS: -- I have not.
BY MS. DALY:
Q In your report, page 1, in your last bullet point, you say "The filter was used as intended, properly implanted, and there were no other causes for failure."
With respect to Ms. Mulkey, do you have any information about why her doctors made the decision to implant her with the IVC filter?
MR. O'CONNOR: Form.

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THE WITNESS: Well, I've read some medical records and the information may be in there, but I -- I don't recall the reasons from that.
BY MS. DALY:
Q Do you recall that she had recurrent DVT and PDN and was about to undergo surgery at the time?
A I may have read that, but I don't recall that specific information.
Q With respect to your comment on proper implantation, do you defer to either Hurst, Muehrcke or other medical specialists to give the opinion whether it was a proper implant?
A I defer to Drs. Hurst, Muehrcke and the implanting -- implanting physician.
Q Okay. With respect to your comment "no other causes of failures of the filter," do you agree that you have not done anything specific to Ms. Mulkey to determine information about her anatomy, medical conditions, medical history or comorbidities?
A I have done --
MR. O'CONNOR: Object to form.
THE WITNESS: -- nothing concerning those issues.

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BY MS. DALY:
Q If there was a fracture in her filter, do you agree that we -- do you have any information that anybody has been able to examine the filter itself or this alleged fragmented piece?
MR. O'CONNOR: Form.
THE WITNESS: It appears that both the filter itself and the fragment are -- at the time of writing of this document, were still in Ms. Mulkey, and, therefore, it's not been possible to examine those pieces of the filter.
BY MS. DALY:
Q Okay. You conclude that the events that occurred in Ms. Mulkey's filter are consistent with the kinds of failures that we've discussed in this deposition and in your reports in the litigation, correct?
A That's correct.
Q All right. But you've not attempted to model or do any calculations of Ms. Mulkey's vena cava size, her respiratory rate, Valsalva experience, her vena cav- -- cava or surrounding organ and vessel tissue or stiffness, nor have you done any modeling of any -- the extent of her perforations, the degree of any tilt that her

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filter experienced, the extent to which it was catching clots to calculate what strains may have been in play on Ms. Mulkey's filter at any time --
MR. O'CONNOR: Form.
BY MS. DALY:
Q -- while it's been in situ?
A I have --
MR. O'CONNOR: Objection. Form.
THE WITNESS: I have not done anything on those issues specific to Ms. Mulkey.
BY MS. DALY:
Q Okay. Let me look at my notes.
You cannot say to a reasonable degree of engineering probability that any given Bard filter in any given patient will have any complication?
MR. O'CONNOR: Form.
THE WITNESS: I can say to a reasonable degree of probability that it is likely that there will be some complications in a population of patients, but I cannot specify that for any individual member of that population.
BY MS. DALY:
Q And can you determine what percentage of population of people with Bard filters will experience any complication?

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MR. O'CONNOR: Form.
THE WITNESS: No, I cannot, but there will be some fraction of the population will experience complications, and that is predictable.
BY MS. DALY:
Q But not the individual?
MR. O'CONNOR: Form.
THE WITNESS: Not for any individual without information that would be a challenge to gather.
BY MS. DALY:
Q And not -- not the rate at which it will happen?
MR. O'CONNOR: Form.
THE WITNESS: Well, for an individual it would either happen or it wouldn't, so I'm not quite sure what that question means.
BY MS. DALY:
Q For the population.
A For the population, again, if one has enough information about distributions of all the attributes of the population, that kind of assessment could be made, but that information would be a challenge to collect, so...
Q And you have not done that?

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A I have not done that.
Q Okay. Thank you, Dr. McMeeking.
MR. O'CONNOR: Okay. I've got some follow-up. I'll just come over there so you're not looking over at me.
(Brief pause.)

EXAMINATION
BY MR. O'CONNOR:
Q Dr. McMeeking, if you would, find the three general reports we've been talking about today.
A Okay.
Q And I think it's a report dated March 3, 2017; another report dated April 7, 2017; and a report dated May 11, 2017. Am I right?
A Yes. So Exhibit 2 is report dated --
Q That's March 3.
A I'll find it. I'm just double-checking. It's dated March 3, 2017. Exhibit 3 is a report dated April 7, 2017. And Exhibit 4 is a report dated May the 11th, 2017.
Q And in addition, we marked your five Bellwether individual reports today, correct?
A That's correct.

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Q Any other reports that were marked today that you prepared?
A That I prepared? I don't believe so, no.
Q All right. Now, Dr. McMeeking, do the reports that you've talked about today, the ones we just listed, do those set forth your opinions and the bases for the opinions that you've arrived at that are to a reasonable degree of engineering probability?
A Yes, they do.
Q And in arriving at your opinions, did you follow a methodology?
A I did.
Q Did you follow a methodology that is utilized by engineers in your field to solve and resolve engineering problems?
A Yes, I used the standard method knowledge that's used by engineers in my field across a broad range of -- of engineering problems, in addition -- and, in addition, that I used specifically in addressing design analysis and testing of medical implants for companies that manufacture such devices.
Q Did you exercise the same level of intellectual rigor that's used by engineers,

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whether in litigation or outside of litigation, to -- to address engineering issues and engineering problems?
A I did.
Q Let's just talk about one of your opinions. Based upon your assessment of the Bard filters, the Bard retrievable filters, the G2, the G2X, the Recovery, the Eclipse and the Denali and Meridian, is it your opinion that failure modes that we've talked about, tilt, perforation, migration and fracture, are predictable based upon those designs?
A Yes, they are.
Q Is that an opinion that you hold to a reasonable degree of engineering probability?
A I do.
Q Now, in your opinions, you talked about calculations that you performed?
A Yes.
Q Was it necessary to perform calculations on each of the model filters or were you able to use calculations that you have arrived at and apply those to the Bard filter and Bard filter models?
A I was able to do calculations for certain models and then make use of the results of those

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calculations to understand and make a -- come to opinions on the other models that I did not do specific calculations for.

Q And could you tell us, you described some through, but tell us the types of calculations, the types of analyses, that you performed in arriving at your opinions in this case.

A Well, I did Euler-Bernoulli beam calculations to look at the strains induced in the limbs of filters as the vena cava expands and contracts. I looked at some finite element calculations for the same problem. I carried out finite element calculations to look at the phenomenon of tilt in -- of the filter in the vena cava.

Q To arrive at the opinions, was it necessary for you to engage in any type of testing such as bench testing?

A No, it wasn't necessary for me to carry out any bench testing.

Q Why?

A Because I had information that was available to me from tests carried out by Bard and, in addition, I had my engineering analysis which enabled me to assess the phenomenon that would take

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place in the filters in the circumstances that I described.

Q Your report -- and you were asked some questions today about Bard testing and Bard analyses, so let's just talk about testing. Have you reviewed the testing, bench testing, that Bard did of its filters?

A I've reviewed a lot of the bench testing that Bard did of the filters.

Q And what is your opinion about the bench -- the testing, including bench testing, that Bard did?

A That the testing that they undertook was inadequate and that it was not at a level that would enable them to understand the failures that are likely to occur in the filter.

Q Explain your opinion, if you will.

A Well, for example, they didn't identify the worst-case conditions that the filter would experience, and they didn't test the filter in conditions that would reproduce such worst-case conditions.

Q Do your reports detail your opinions about the inadequacy of testing?

A Yes, they do.

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Q And when you talk about worst-case scenario, is that a standard that engineers are required to follow?

A Yes, in dealing with this kind of problem, engineers are expected and required to identify the worst-case conditions and then take that into consideration when assessing the performance of their design and the consequences of -- of the design.

Q Now I want to -- I want to move around a little bit. Well, let me ask you about calculations and analyses. You talked about the ones you've performed. In your work in this case, did you look at and review the types of calculations, the engineering analyses, that Bard performed?

A I reviewed finite element calculations that they performed.

Q And do you have an opinion about whether those were sufficient or adequate?

A Almost all of them were inadequate for various reasons.

Q What were the reasons, among the reasons, please?

A Well, some of the reasons were that it was

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clear that they were not carried out in a reliable manner and the results looked inconsistent with each other within sets of calculations and comparing some calculations from one set with calculations from another, and that this was not scrutinized in a way that would enable the discrepancies to be understood so that the calculations could be carried out in a reliable and accurate manner.

In addition, the assumptions that went into the calculations were almost always not appropriate for the calculations that were being done, such as the constraints on the motion of the components of the filter and the way that the calculation was carried out to ensure that accurate results were obtained.

Q If the tests -- the analyses that Bard performed were -- did take the step to be reliable and were accurate, as you suggest they were not, do you have an opinion whether Bard would have known that its filters were predictably going to fail?

A Yes.

MS. DALY: Object to form.

THE WITNESS: Those results, when accurately computed, would have revealed that there

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were failure modes that would be predictable when the filters were implanted in patients.
BY MR. O'CONNOR:
Q Does that include migration?
A That includes migration.
Q Fracture?
A Fracture.
Q Tilt?
A Tilt.
Q And perforation?
A And perforation.
Q You were asked questions about the Denali filter. You have evaluated the Denali filter?
A I have evaluated it in -- in -- in terms of its features that make it similar and different from other models in the -- in the Bard line of filters.
Q And have you determined that the design of the Denali fil- -- filter will cause it to predictably fail?
A Yes.
Q And what is the based -- what is that opinion based upon?
A Because it is very similar in shape and configuration to the other filters which also --

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which themselves are subject to failures, and the analysis that I've done on the various Bard filters indicates that such failure modes will be present in them. And because of the similarities that the Denali has with the ones that I analyzed, one will expect the same kind of failures to occur in the Denali.
Q You discussed your reports do cite references to medical literature and other literature?
A That's correct.
Q And did that literature that you reviewed appear to have consistent findings that were consistent with your opinions in this case?
A Yes, the observations of -- of the medical literature in terms of the failures that were observed in implanted filters were consistent and support the conclusions and opinions that I drew in regard to the behavior of those filters and where my opinions were based on my calculations.
Q For example, you were asked questions about an article written by Dr. Stavropoulous on the Denali filter. Do you remember that?
A That's correct.
Q And in that article, did it talk about

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dwell time?
A May I look at the report?
Q Please.
A So that's Exhibit No. 12 and -- so in the abstract it says "The mean filter dwell time at trieval" -- "at retrieval was 200.8 days and the range was 5 to 736."
Q And -- and was there a limit in the number of filters that were studied, patients?
A There were 200 patients that were studied.
Q Now, you mentioned something earlier in your testimony, you talked about the filters, the Recovery, the G2, the G2X, the Eclipse, the Meridian and then the Denali. You mentioned that these filters were permanent filters?
A The Recovery through the Denali were optional filters, which means that they can be implanted as permanent filters with an option to retrieve.
Q And was your point earlier that -- being permanent, that the design should be one that will not fail after it's implanted in a patient?
A Yes. Yes. My --
MS. DALY: Object to form.
THE WITNESS: The important point is if a

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filter is to be used as a permanent filter, it should be able to deal with the lifetime environment that that filter will experience during implantation.
BY MR. O'CONNOR:
Q And when --
A Since it will remain in the patient until death, presumably.
Q When you look -- did your work in this case and read the medical literature, I think you talked about this before, but due to the design deficiencies, these dangerous designs, do you have an opinion that there is a relationship that as they stay in a patient, there's a greater likelihood of failure?
MS. DALY: Object to the form.
THE WITNESS: Yes, since the failures that I observed are -- or that I've dealt with are all progressive and the tilt tends to be progressive and increases over time, perforation is progressive and increases over time, and fracture is a progressive phenomenon in that it takes cycles of loading for the fatigue damage to ultimately cause fracture of the component, that is also a time-dependent phenomenon. And, therefore, the

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longer the filter is in a patient, the greater is the likelihood that failure will occur.
MR. O'CONNOR: Thank you.
I just got a message that the phone has been disconnected.
MS. DALY: Maybe it has a length of time that it will do a conference call. Probably -- that's probably it. We're probably over the time that the thing allows.
MR. O'CONNOR: I wonder how we can reconnect the people in.
THE COURT REPORTER: Can we go off the record?
MR. O'CONNOR: Yes.
THE VIDEOGRAPHER: We're going off the record at 1705.
(Recess taken.)
THE VIDEOGRAPHER: We are back on the record at 1706.
BY MR. O'CONNOR:
Q Now, in your work, you have analyzed each of the failure modes, correct?
A That's correct.
Q You were asked some questions and you talked about Dr. Briant's reports, correct?

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A That's correct.
Q And you testified about some assumptions that he made regarding the vena cava filter, true?
A That's correct.
Q You were talking about a Laborda article. Now, did Dr. Briant cite a Laborda article in his report?
A Well, he cited one Laborda article in his report, and he also cited an article that said that there were Cook filters involved in the experiment.
Q Was his citation correct?
A The citation was incorrect because he referred to the one Laborda, et al., paper that did not have any filters involved in the -- in the -- in the work, and, therefore, it was -- it was a mis-citation of the relevant paper.
Q When you went and did your research, did you learn about the mis-citation?
A Well, I read his report and noted that he had referenced a paper erroneously, and I then tried to find the paper that would be consistent with what he was saying he was citing, but at that stage I could not find it in time to make use of it to carry out my assessment of that paper.
Q And you finally found the report?

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A Yeah, I finally found the paper and was able to make use of the information within that paper.
Q All right. And assuming that was the paper that Dr. Briant was referring to, did he cite it correctly?
A He -- if it was the paper he meant to cite, he did not cite it correctly.
Q And where was he incorrect?
A Well, you -- when I say "cite," I mean provide the location where the paper is to be found. Are you asking -- is that -- can you clarify the question?
Q Did he represent the article -- the information in that paper correctly?
A Well, he stated that it showed that a Cook filter would significantly impede the contraction of the vena cava during the relevant motion that was imposed on it, and that seemed to, in my -- in my interpretation "significant" means that the compression would be much less than the compression that would occur in the absence of the filter; whereas, the data in the paper shows that the compression of the vena cava at the filter is two-thirds that which occurs in the absence of the

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filter.
And to me, that's -- that's a -- I note that that's a -- there's a reduction in the compression, but I would not interpret that as a significant reduction in the compression.
Q And is that consistent with the opinions that are set forth in your reports?
A Sorry, could you repeat that question.
Q Well, when you talked about today, when you talked about that the misinterpretation by Dr. Briant, have you discussed those issues in your earlier reports?
A Well, I've discussed it in that I've always taken the position that the filters will not impede the motion to any significant extent of compression of the vena cava, and so I've addressed that in various reports and rebuttals that I've provided in various cases.
Q Now, you were asked questions about a linear and nonlinear report -- approach, and you used the linear approach in your calculations; is that correct?
A I used linear elastic analysis for certain calculations which are to be done by linear elastic analysis because that's the behavior of the

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material in the conditions involved.
Q And is that the appropriate methodology that --
A That's --
Q -- engineers should follow?
A That's the appropriate methodology that should be followed in that case.
Q So when you were talking about the sheath and arm relationship, is that a linear issue?
A So can you clarify that question.
Q Well, give me examples of why linear is appropriate in your analysis.
A Oh, because in the cycling of the strains the filter experiences within the vena cava, within a certain range, the cycling will motivate only linear elastic behavior of the material in the filter.
Q On this issue of the cap, is con- -- is contact between the cap and an arm necessary for fracture?
A No.
Q How can a fracture related to the cap occur without direct contact?
A Well, the -- the fracture that I'm describing is one that would take place in the arm

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in the high strain location near the cap, but it doesn't necessarily occur exactly at where the wires of the limbs enter the cap. And so the fracture that takes place a little distance away from the edge of the cap will occur whether the arm itself is touching the cap or not in the circumstances that we're describing.
Q By the way, is it necessary for you to look at an exemplar filter to render your opinions in this case?
A No, it's not.
Q Was it necessary for you to look at explanted filters to explain the cause of filter fractures?
A No, it's not.
Q Did you use appropriate methodology and appropriate foundation to arrive at those opinions?
A Yes, I did.
Q Was it necessary for you to do tests and test -- and look at test results in this case?
A It was not necessary for me to do bench tests or any other kind of tests to come to my opinion.
Q Why not?
A Because I based my opinions on the

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calculations that I carried out, and that was sufficient for me to form the opinion that I did.
Q All right. And I'm getting close here. You were asked questions about opinions that you have about the Simon nitinol filter, correct?
A Correct.
Q And you have talked about the Simon nitinol in terms of it is better in terms of failure modes than the other Bard filters; is that correct?
A That's correct.
Q Have you seen Bard internal documents that indicate that the Simon nitinol filter was regarded by Bard to be a better filter in terms of failures and failure modes compared to its other models of filters?
A Yes, I've seen copies of e-mails by Dr. C- -- I can't quite say it correctly -- Cierrela, that refer to the Simon nitinol filter as a better filter than other filters in the Bard line.
Q Why were you -- can you explain the reason that you compared the petal of the Simon nitinol filter to the arm of the Recovery and the G2?
A Because they are elements of the

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various -- of the two filters that play similar roles in the two filters.
Q The medical articles that you've reviewed about the Simon nitinol filter, including the Poletti, have those affected your opinions at all?
A No, they have not affected my opinions.
Q Do those articles support your opinion that the Bard is a better filter -- I mean that the Simon nitinol is a better filter in terms of failures?
A Since the Poletti article comments that the Simon nitinol filter is a safe filter, I use that information in the paper to support my view that the Simon nitinol is a safer filter than the other ones.
Q All right. Now, let's talk about your case-specific opinions. To arrive at the opinions you did in each of the five Bellwether cases, that would be Booker, Jones, Kruse, Mulkey and Hyde, correct?
A Correct.
Q Was it necessary for you to do any calculations specific to those patients?
A No, because the failures that were observed in them were consistent with the

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predictable failures that I identified as a consequence of my analysis of the Bard filters.
Q Did you follow the type of methodology that engineers should follow when they are looking at failures and failure modes of medical devices such as filters when you arrived at your opinions in the five cases?
A Yes, I did.
Q And did you rely on the work you did in your prior reports?
A I did, yes.
Q Does it matter to your opinions whether the Hyde filters are G2 or G2X?
A No.
Q Why not?
A Because they're -- they're essentially similar. They have only the difference that there's a hook on the cap and there's a slight difference to the details of the shape of the cap, but the detail differences are not big enough to make a difference to the fatigue behavior of the G2X compared to the G2 in any significant way.
Q And Ms. Hyde had a fractured leg in the ventricle of her heart?
A I'd have to look at the reports to --

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Q Could you quickly, just to verify that.
MS. DALY: I'll stipulate to it.
BY MR. O'CONNOR:
Q And -- and the point is is that that failure was spelled out clearly by both Dr. Muehrcke and Dr. Hurst, true?
A That's -- I need to look at the reports, but yes, that's my recollection.
Q And do you need to inspect Mrs. Hyde's filter or any filter to understand how the design resulted in the failure mode in each of the five?
A No, I don't need to carry out specific inspection of the filter because it's the design itself that is the cause of the dangerous failures that take place.
Q Is it necessary for you in any of the five Bellwether plaintiffs to know anything of a specific event, such as Valsalva, the size of their vena cava?
A No, I don't need to know anything specific because the design makes it probable that there will be failures of filters in patients.
Q And is your opinion the same as it relates to blood flow, comorbidities and whatever -- and whether they have any impact?

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A Yes, that's my opinion.
Q You don't need to know that information?
A I don't need to know that information.
Q And that's something that would not be necessary following the appropriate methodology that engineers follow when they arrive at their opinions --
A That's correct.
Q -- regarding failures?
A That's correct.
Q Was it necessary for you to do specific models or calculations in any of the five Bellwether cases?
A No.
Q A fracture is the result of fatigue?
A Yes. Correct. If the process goes on long enough, fracture is the result of that fatigue.
Q And the same thing: To follow the appropriate methodology, was it necessary for you to know anything about the tissue quality of any of the five Bellwether plaintiffs or their vena cava, their organs or blood flow or respiratory issues?
A No, because it's -- knowing, for example, that Bard filters are the type we're talking about

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perforate the wall of the vena cava, and that is sufficient to provide me with information that allows me to come to my opinion.
Q And again, are the opinions that you've arrived at in the five Bellwethers, as well as the opinions that you have arrived at in your MDL reports, opinions to a reasonable degree of engineering probability?
A And reasonable degree of engineering certainty, yes.
Q Thank you.

FURTHER EXAMINATION
BY MS. DALY:
Q Dr. McMeeking, to the extent that any of the work that you have done in this case makes assumptions that are inaccurate, then the outcomes of the calculations would be different?
MR. O'CONNOR: Form and foundation.
THE WITNESS: That's always the case. If the assumptions are not correct, then the analysis is -- is not relevant. Although the degree of relevance may depend on how poorly the assumptions have been drawn.
BY MS. DALY:

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Q Right. With respect to what Mr. O'Connor just asked you about, the citation by Dr. Briant to the Laborda paper, you don't have any reason to believe that Dr. Briant purposely mis-cited the paper, do you?
A You mean mis-cited in the terms of stating what was in the paper or --
Q Telling you --
A -- where to find it?
Q Where to find it.
A I have no reason -- I know nothing about why it was mis-cited.
Q Okay. And in fact, as we talked about both today, Laborda had two similar papers published a year apart, right?
A I -- I think it's a year apart, yes, that's correct.
Q And the Laborda paper was easy to find by like Googling the author's name, true?
A But I didn't know it was a Laborda paper.
Q Okay.
A And I should comment that in terms of standard of work, it's -- it's a problem if you don't cite sources of information properly.
Q Right. Like Dr. Muehrcke, correct?

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MR. O'CONNOR: Object to the form of the question.
BY MS. DALY:
Q All right. To the extent --
MR. O'CONNOR: Argumentative.
BY MS. DALY:
Q To the extent that you did analyses in this case, you state that for those analyses you employed appropriate engineering principles, correct?
A Correct.
Q All right. And you based your opinions on the calculations analyses that you have presented, true -- correct?
A I did.
Q And you said you did not do bench testing that went beyond the analysis, so you did not use actual testing to determine whether your assumptions and the conclusions you drew from them were accurate, true?
MR. O'CONNOR: Form.
THE WITNESS: That's correct.
BY MS. DALY:
Q And you have not devised a filter that you claim would have resolved the various complications

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we've talked about today, true?
A I have not devised any such filter.
Q And you don't know a filter on the market ever that would -- that exists with a design that resolves all these complications, true?
A I'm not aware of any such filter, although it's -- it's because I don't know the attributes of all filters.
Q And you just testified that you did not have to do bench testing here because you had Bard testing to review; is that what you said?
A That's correct.
Q But you said that was inadequate?
A Yes.
Q Okay. So in not doing your own testing and relying on inadequate testing of Bard, you have no bench testing that will provide us with an example of a better test that Bard could have done, true?
MR. O'CONNOR: Form.
THE WITNESS: Can you repeat the question.
BY MS. DALY:
Q Okay. Yes.
So having not done your own testing and being critical of the testing that Bard did, you

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have devised no testing that you've provided to us that is an example of better tests that Bard could have done?
MR. O'CONNOR: Form.
THE WITNESS: Well, I -- the statement I made is that I re- -- I was able to review the Bard testing and that that is a contributor to my -- my assessment of the situation, but it doesn't mean that I would have to do further, more elaborate bench testing or bench testing under different circumstances to come to the opinions that I came to in -- by using my calculations.
BY MS. DALY:
Q And if your assumptions in your calculations are inaccurate, bench testing might show that?
MR. O'CONNOR: Form. Foundation.
THE WITNESS: Well, I -- I'm not sure if I agree with that. I don't agree with that, because if you do a calculation based on certain assumptions and then you do a bench test with the same assumptions, then you're likely to get the same results from a properly designed bench test.
BY MS. DALY:
Q But you've seen that not happen in the

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world of engineering, true?
A That can happen too, yes.
Q And you have not developed any better tests or different tests that Bard could have done; is that right?
A I've described some tests that I think they should have done, but I've not devised a protocol and plan for carrying those tests out.
Q And having not done that, you have not taken it further to employ those tests to determine what they would show?
MR. O'CONNOR: Form.
THE WITNESS: I have not.
BY MS. DALY:
Q Okay. Now, you said that your analysis shows that tilt, migration, fracture and perforation are predicted based on your analysis, correct?
A Correct.
Q But you will agree that the FDA recognizes that filters can experience any of these complications, true?
MR. O'CONNOR: Form and foundation.
THE WITNESS: I'm aware that Dr. Briant has written statements like that in his report.

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BY MS. DALY:
Q And you're just saying that because you don't know exactly what he recognizes?
A I don't know exactly -- right. Exactly.
Q All right. But having looked at the testing, you know that testing was submitted to the FDA that looked at things like migration, fracture?
A Yes.
Q Okay. And you know also that Bard listed those four complications on its instructions for use as things that can happen, correct?
MR. O'CONNOR: Form. Foundation.
THE WITNESS: Well, I haven't reviewed the instructions for use, so I don't know that for a fact.
BY MS. DALY:
Q On what literature or other information do you rely on your statement to Mr. O'Connor that the end dwell time actually leads to progression of failure modes?
MR. O'CONNOR: Form.
THE WITNESS: Well, I rely on lots of literature in regard to the fatigue behavior of nitinol.

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BY MS. DALY:
Q Okay.
A And I rely on papers that indicate -- papers and information from reports in which the degree of perforation at one stage is greater -- sorry, let me start again with that.
So that as time passes, the degree of perforation increases as time passes, and, therefore, that perforation is a progressive phenomenon.
Q What about tilt?
A Again, there are reports in the literature and in technical reports, such as in this case, that the tilt increases with time in some cases.
Q What about migration?
A I -- I can't comment on migration.
Q And we've seen in cases that you've given reports on in this litigation and in some of these Bellwether cases that there appears to be no evidence of progression, true?
MR. O'CONNOR: Object to the form.
THE WITNESS: Can you clarify the question.
BY MS. DALY:
Q Sure.

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We just went through some Bellwether cases in which there was no data showing a progression of perforation in some cases or a progression of tilt?
A In some cases there's no information on that, but it doesn't mean that progression didn't occur.
Q But you don't have any information to back it up?
A In -- in certain cases there is no specific observation that backs that up.
Q Okay. With respect to the SNF, one last thing, the bottom line on the SNF filter is that it cannot be retrieved percutaneously due to a number of reasons related to its design, fair?
MR. O'CONNOR: Form.
THE WITNESS: It's a permanent filter, yes.
BY MS. DALY:
Q And it -- and, therefore, it does not provide the same benefits as the Bard retrievable filters in that it cannot be percutaneously retrieved, true?
MR. O'CONNOR: Form. Foundation.
THE WITNESS: I'm not a medical expert, so

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I can't comment on that.
BY MS. DALY:
Q You can't comment on the fact that the SNF is not readily percutaneously retrievable?
A No, I meant that I can't comment on the benefits of having a retrievable filter. That's what I meant. Because I'm not a medical expert.
Q Okay. We'll just leave it at the SNF you know is not readily percutaneously retrievable?
A Correct. I agree.
Q All right. Thank you very much.

FURTHER EXAMINATION
BY MR. O'CONNOR:
Q Just to clarify, the calculations you've done in this case and -- and the assessments you've done, you followed the appropriate methodology, correct?
A Correct.
Q Does that methodology require you to do bench testing?
A No.
Q And in terms of Bard's bench testing, your qualifications and what you did, you followed

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appropriate methodology to assess their bench testing?
A I did, and I used that methodology when I consult for medical implant companies, assessing their testing and interpreting it and advising them whether it's being done adequately or whether improvements to the testing should be undertaken.
Q And in this case you determined that the testing was inadequate?
A I did.
Q And that it failed to provide information showing that these filters would fail?
A That's correct.
Q Okay. That's all I have.
And that's an opinion you hold to a reasonable degree of engineering certainty?
A I do.
MR. O'CONNOR: Thanks.
THE COURT REPORTER: Do you read and sign?
MR. O'CONNOR: We'll read and sign.
THE WITNESS: I will read and sign.
THE VIDEOGRAPHER: We are off -- excuse me. We are off the record at 1729, and this concludes today's testimony of Robert McMeeking,

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Ph.D. The total number of media used was five and will be retained by Veritext Legal Solutions.
(Whereupon, at 5:29 P.M., the videotaped deposition of ROBERT M. McMEEKING, Ph.D. was adjourned.)

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STATE OF CALIFORNIA)
COUNTY OF SANTA BARBARA) ss.

I, MONICA T. CORLEY, RMR, CRR, CSR No. 8803, in and for the State of California, do hereby certify:
That, prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify the truth, the whole truth and nothing but the truth;
That said deposition was taken down by me in shorthand at the time and place therein named and thereafter reduced to typewriting under my direction, and the same is a true, correct and complete transcript of said proceedings;
That if the foregoing pertains to the original transcript of a deposition in a Federal Case, before completion of the proceedings, review of the transcript { } was { } was not required.
I further certify that I am not interested in the event of the action.
Witness my hand this 19th day of July, 2017.

Certified Shorthand Reporter
for the State of California

1

TO: Mark O'Connor
Re: Signature of Deponent Robert McMeeking , Ph.D.
Date Errata due back at our offices: 08/19/2017

Greetings:
The deponent has reserved the right to read and sign. Please have the deponent review the attached PDF transcript, noting any changes or corrections on the attached PDF Errata. The deponent may fill out the Errata electronically or print and fill out manually.

Once the Errata is signed by the deponent and notarized, please mail it to the offices of Tiffany Alley (below).

When the signed Errata is returned to us, we will seal and forward to the taking attorney to file with the original transcript. We will also send copies of the Errata to all ordering parties.

If the signed Errata is not returned within the time above, the original transcript may be filed with the court without the signature of the deponent.

Please send completed Errata to:
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(770) 343-9696

2

ERRATA for ASSIGNMENT #
I, the undersigned, do hereby certify that I have read the transcript of my testimony, and that

___ There are no changes noted.
___ The following changes are noted:

Pursuant to Rule 30(7)(e) of the Federal Rules of Civil Procedure and/or OCGA 9-11-30(e), any changes in form or substance which you desire to make to your testimony shall be entered upon the deposition with a statement of the reasons given for making them. To assist you in making any such corrections, please use the form below. If additional pages are necessary, please furnish same and attach.

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DEPONENT'S SIGNATURE

Sworn to and subscribed before me this ___ day of
_____, _____.

_____
NOTARY PUBLIC
My Commission Expires:_____

EXHIBIT C

In The Matter Of:

NEWTON v.

BARD

ROBERT MAXWELL MCMEEKING, PH.D.

May 24, 2011

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IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
IN AND FOR THE COUNTY OF MARICOPA

KATRINA NEWTON, et al.,
Plaintiffs,
vs.) No. CV2009-019232
C. R. BARD, INC., et al.,) No. CV2009-035781
Defendants.

RICHARD KOLENDA, et al.,
Plaintiffs,
vs.
C. R. BARD, INC., et al.,
Defendants.

DEPOSITION OF ROBERT MAXWELL MCMEEKING, PH.D., taken on behalf of Defendant, commencing at 2:03 p.m., Tuesday, May 24, 2011, at 420 East Carrillo Street, Santa Barbara, California, before ELIZABETH A. MOOY, CSR #11281, Certified Shorthand Reporter in the County of Santa Barbara, State of California.

--oo0oo--

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ALSO PRESENT:

MATTHEW R. BEGLEY, PH.D.

VIDEOGRAPHER:

FRANK J. KAP, CLVS

I N D E X

E X H I B I T S

(14:04:01-14:04:29)

VIDEOGRAPHER: Good afternoon. This is the videotaped deposition of Robert Maxwell McMeeking, Ph.D., in the matter of Katrina Newton, et al., versus CR Bard, Inc., the case pending in the Superior Court of the State of Arizona, in and for the County of Maricopa. The case number is CV 2009-019232. Today's date is Tuesday, May 24th, 2011, and the location is 420 East Carrillo Street, Santa Barbara, California. The time on the monitor is 2:03 p.m. The Certified Shorthand Reporter is Liz Mooy. My name is Frank Kap. I'm a Certified Legal Video Specialist and I represent D'Amico Gershwin Court Reporters located in Atlanta, Georgia.

Would Counsel and all present please introduce yourselves for the record and state whom you represent.

MR. HARTLEY: Dean Hartley on behalf of plaintiffs.

MS. DALY: Taylor Daly for Bard.

THE WITNESS: Robert McMeeking, appearing for the plaintiff. Expert witness.

MR. BEGLEY: Matthew Begley, expert witness for the plaintiff.

MS. DALY: We can have the same stipulation as for Dr. Begley's deposition.

MR. HARTLEY: Yes.

(14:05:04-14:05:32)

ROBERT MAXWELL MCMEEKING, PH.D.,
Having been first duly sworn by the
Certified Shorthand Reporter, testified as follows:

EXAMINATION

BY MS. DALY:

Q Dr. McMeeking, I'm Taylor Daly. We met earlier today, and you sat through the deposition of your colleague, Dr. Begley?

A Yes.

Q You were present when we talked about -- at the beginning of his deposition -- trying to efficiently take your deposition, and you and he presented a joint report; correct?

A That's correct.

Q And what we discussed was that you would try to take some notes and you would be able to then add to any of the questions that I ask Dr. Begley, correct anything that he said that you thought should be different, and so on; correct?

A Correct.

Q My intent is not to shortcut your deposition; rather, it is to be efficient. So please feel free that you can answer any of the questions as fully as you want. I'm not holding you to what Dr. Begley said in any way.

(14:06:23-14:07:03)

Do you understand that?

A I understand that, yes.

Q Very good. Would you tell me, what would you describe as your general expertise?

A My general expertise is mechanical engineering and materials science, more specifically the modeling and analysis of the mechanical and functional behavior of materials and the fairly significant focus on medical devices.

Q What medical device work have you done either as part of litigation or non-litigation consulting?

A The one litigation case was a long time ago. It was a failed -- a bicycle broke while the rider was on it. It was 20 years ago. But the balance of my work on medical devices has been consulting for medical device companies. The biggest area has been prosthetic heart valves. In addition, I've done consulting work on some stents for various purposes, and another area that I've worked on is breast implants.

Q Have any of the heart valve products or the stent products involved Nitinol use?

A Yes.

Q Which ones?

A There are a couple of heart valves that are in the pre-market stage of being looked at by the companies

(14:08:02-14:08:46)

and the FDA. They are balloon expandable and they use the Nitinol behavior specifically in the way that they're implanted into the heart; and in addition, a stent that is expanded into arteries to clear the stuff that gets stuck to the wall in -- when the artery is diseased.

Q Are the heart valves made of Nitinol themselves, or did you just say they had Nitinol-like memory characteristics?

A Well, they have Nitinol stents or -- I've forgotten the word for them -- but one component of the device is Nitinol, and sewn onto the Nitinol are tissues. Usually they come from pig pericardium, and the tissue functions as the actual occludo that controls the flow of the blood through the valve.

Q For either the stent consulting that you did or the heart valve work that you did, did you develop any modeling for those companies that was a part of their design work?

A Not as part of the design work, no.

Q What was it a part of?

A It was a part of the reliability assessment of the valve that was needed both for assurance of the safety and reliability of the device -- not just the valve, but of the device -- and also to take forward to the FDA to obtain licensing of the device for either

(14:09:45-14:10:19)

pre-market or eventually full sale activity for the device involved.

Q In that case, did the FDA require the kind of -- was an FEA the modeling that you did?

A Well, some of it was FEA modeling. I looked at the way that fluid can lower the devices, I looked at the way that tissue to which the device is sewn or implanted can lower the devices, and looked to the effect of residual stress that can be present within the device in the case of carbon valves, and looked at all those features in a variety of ways that involved calculations and modeling. Some of it was finite element modeling to identify the levels of stresses which were involved in the way that the devices function.

Q Do you know if the work that you did, the modeling you did, was something that was required by the FDA for clearance of that particular type of device?

A Yes, yes. And in some cases, the FDA directed companies to me to carry out that kind of work.

Q And the IVC filters that we're talking about here, you are aware that the FDA has never required that type of modeling; correct?

A I'm not aware of what the FDA requires for these devices.

Q Following up on that, do you consider yourself

(14:11:21-14:11:59)

to be an expert in FDA regulatory approval processes?
A I guess I'm an expert in part of the process. I would not claim that I'm an expert in every single feature of the FDA approval process because that involves animal modeling, clinical work; it involves a question of shelf life, packaging, and also sort of aspects of the -- how the device will be implanted, used, and operated with and so on.
Q Which you don't do?
A Which I don't do, but I'm aware of a great deal of the process because of my involvement in the sector that involves safety and reliability of the devices.
Q With respect to the IVC filters, did you review any of the submissions that Bard made to the FDA either for the permanent or the retrievable recovery filter?
A I read through one 510(k) submission. I don't remember whether it was for the recovery or the other device, but I did read through a 510(k) submission.
Q Was there anything in that 510(k) submission that informed you in any way that helped you write the report in the case?
A Yes. For example, I read carefully the -- I mean, I read them all carefully -- but I read specifically the description of the fatigue test that was carried out on that device, the way that the device was

(14:12:55-14:13:33)

placed inside the tube, and the tube was expanded and contracted to carry out the fatigue test, and that guided me in my thinking as to what would be the appropriate things to look at in the modeling and analysis of the stresses that can be generated in the device, and also it helped me think about what testing should be done to obtain further information about the performance of the device.
Q So some of the -- the testing that you just described that you saw in the 510(k), you did use aspects of that when you modeled one or both of the FEAs that you and Dr. Begley did?
A When I discussed how we should go about modeling, that did inform my thinking about what we should do, such as, move the end of the arm by one millimeter to simulate the way that loading could occur to the device when it is en vivo.
(Exhibit 1 was marked for identification.)
Q Okay. Let me show you Exhibit 1 that I've marked for your deposition, which is the Notice of Deposition in this case. And if you would just turn to page 4 that has the list of materials, is there any additional article or publication -- again, other than some major fluids textbook -- that you refer to during the investigation of this matter that is not listed in

(14:14:39-14:14:59)

your report on page 7?
A No, all of the material that I've looked at and relied upon is listed on page 7 and, of course, there's also the list of all the Bard reports that --
Q Correct, and I'll ask you that in a minute. Have you had a chance to look, actually, at the letter from Jack Davis with the list of Bard materials?
A I haven't looked at it recently, but --
Q Have you looked at it in the past?
A Yes.
Q Are you able to confirm that's what you reviewed?
A Yes.
Q And that it was limited to that?
A It was limited to that.
Q All right. Let me just, for the record, put this in. This is Exhibit 5, actually, to your deposition and be sure we're talking about the same letter and the same list.
A Well, I haven't memorized all the numbers.
(Exhibit 5 was marked for identification.)
Q BY MS. DALY: Of course.
A But it looks consistent with the list of reports that we have in our possession and that we have looked through.

(14:15:29-14:16:08)

Q There was a memorandum and it's the last item on the list. There was a memorandum by one of plaintiff's attorneys whose name is Michael Prascik. Do you remember that memo?
A No, I don't.
Q Do you remember ever going through that memo to ask him to get you anything in addition that was listed on his memo?
A Sorry, could you repeat the question.
Q Do you ever recall reviewing that memo and asking plaintiff's counsel to get you anything else listed on that memo that you thought was relevant?
A Well, I don't remember -- since I don't remember the memo, I don't remember it that way. What I do remember is asking plaintiff's counsel to obtain material of a specific nature, such as finite element analyses, descriptions of anything that might relate to how the device is loaded, and anything else that was related to those two issues.
Q Okay. So the list that is part of this letter from Jack Davis, Exhibit 5, is in response from plaintiffs to that sort of general request by you; is that correct?
A I believe so, yes.
Q And you don't know what else is out there that

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is a Bard document that might fall within the category of what you just described?
A Since I haven't seen it, I don't know. Since I haven't seen them, I don't know.
Q Do you have any patents?
A I have, I think, three. I'm not sure exactly what -- I've forgotten the number, but three or four.
Q What do they relate to?
A They relate to -- nothing to do with medical devices. One of them is maybe a little bit related which has to do with adhesion, dry adhesion, and the patent surfaces that you would use to make one surface stick to another. The other ones were analytical systems for analyzing manufacturing processes.
Q So have you ever designed a medical device?
A No.
Q Have you ever done a study of or written an article on an implantable medical device?
A I -- actually, I forgot to look through my CV to count it, but I think it's two. I have two papers that are on heart valves, and safety and reliability of heart valves, which, of course, are implantable devices.
(Exhibits 2 and 3 were marked for identification.)
Q BY MS. DALY: Let me show you what we've marked

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(14:18:14-14:18:40)

as Exhibit 2 and ask you to identify that.
A That's my curriculum vitae.
Q Do you believe it's an up-to-date one?
A Easiest thing is to look at the last page. It's almost up-to-date. There's one or two papers been added to my publications list and maybe one or two lectures or seminars that I've given that have been added more recently than this version.
Q But don't have anything to do with IVC filters?
A Nothing to do with IVC filters.
Q All right. You stated in your report that you have not given trial or deposition testimony in litigation in the last four years?
A Correct.
Q How about four years before that?
A Never. I've never -- the few cases I've been involved in were settled before even depositions were taken.
Q Very good. I'm going to hand you Exhibit 4, actually, to Dr. Begley's deposition, which are two billing letters that he provided, one January and one May of 2011, and ask you if those are accurate joint billing letters for your time at Dr. Begley's?
A Yes, they are.
Q Thank you. Will you state what your

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(14:19:48-14:20:31)

understanding is of your role as an expert in this filter litigation?
A My role was to make an assessment of the device in terms of the loads that could be applied to it and to work -- to assess how high the level of stresses would be as a consequence of the kind of loads the device would experience, and to make an assessment of whether there were concerns that that raised as to the safety and reliability of the device.
Q Okay. You were not asked to look at any particular plaintiff's filter and come to a conclusion about what had caused that particular fracture in that particular filter?
A Well, I was asked to look at pictures of the devices that had failed, and as Professor Begley mentioned, we did have -- we do have -- we did have one -- I think one filter in our possession which we've looked at visually, and from the pictures that we've looked at, the SEM micrographs that we've looked at, I'm certainly able to make an assessment of why the filters failed, and it's quite clear that the filters failed because of fatigue associated with high stresses that they were experiencing.
Q Are you able to key a particular plaintiff to a particular scenario in your report that that filter

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failure happened because of that particular scenario?
A Only in the sense that we identified -- Professor Begley and I together identified the places where the stresses would be high in the filter as a consequence of the way that they are implanted and the way that they function within the vena cava, and that the location and the nature of the failure is consistent with the fact that we found the possibility of high stresses in those locations in the filter.
Q Do you intend when you come to trial to go through, for example, Mrs. Newton, and testify to the jury from the SEM where her fractures are and how that relates to your findings?
A I intend to testify in the way that I just described which is that we made an assessment of where the high stresses can arise in the device under assumptions that should reasonably have been made by Bard when they designed and analyzed the device, and that the failure that was experienced by Mrs. Newton's filter is consistent with the analysis that we carried out and the observations we made of the filter.
Q Did you have an opportunity to look at Dr. Fasching's report?
A Yes.
Q Do you have any criticisms of her findings on

(14:23:17-14:23:53)

SEM about what fracture looks like what?
A She is, I think, a little too categorical in some of the things that she says. For example, she says that only two of the failures are directly associated with the fact -- or associated with the edge of -- or corner of the sheath; whereas, it is my assessment that several more, a few more of the fractures, can be associated with the fact that the sheath is a component that is causing an increase in stresses in the arms of the device and that she's, I think, been a little bit too tight in the way that she defines association of the fractures with the stress raiser at the corner of the sheath.
Q All right. We'll go through those in a minute. Let me ask you generally about the topics that I was talking to Dr. Begley about and see if you have any additions to that or any corrections to what we were talking about, and then I want to take those premises and I want to walk through these individual plaintiffs.
A Okay.
Q Let's talk first about the chamfer issue. You heard what Dr. Begley said about the chamfer issue?
A Yes.
Q Do you agree with what he said on the issue of chamfer?

(14:24:38-14:25:22)

A I do.
Q Is there anything you would like to add or correct about his testimony on the chamfer issue?
A No.
Q When we say, "The chamfer issue," does that cover all of the different discussions that Dr. Begley and I were having about sharp edges, beveling, chamfering?
A Yes. I'm interpreting the statement that -- the "chamfer" to mean the question of whether the end of the sheath is beveled or flat, whether there is a sharp edge to the sheath where the legs are adjacent to it, or whether there's a larger radius of curvature at that location. So I'm taking it as an all-encompassing question regarding the whole geometry in that area.
Q And what do you rely on for the statement in the report that the filter, the recovery filter as manufactured, is not consistent with a spec with respect to the chamfer?
A Well, the ones that -- the filters that we looked at all have flat ends to the sheath, which was not reflected in the drawings of the devices that we saw -- I saw.
Q Do you know which drawing you were looking at?
A It was a Bard filter. That's all I recollect.

(14:26:13-14:27:05)

Q It's one of the ones on the list in Jack Davis's letter?
A Yes, correct.
Q When you said, "The filters we looked at," are you talking about looking at filters by looking at design drawings of filters, as one way to look at it?
A I mean, looking at the filters both in terms of the design drawings and the SEM images that's in both of the reports, Dr. Ritchie's and Dr. Fasching's.
Q And then again, like Dr. Begley, the only physical filter you've seen is Mrs. Carnehl's G2?
A Correct.
Q Did Mrs. Carnehl's filter that you saw inform you in any particular way about Mrs. Carnehl's filter?
A No, because I didn't even look at it under a microscope. I simply -- it was more interesting just to get an idea of the size and feel of the device and its general configuration.
Q Dr. Begley and I were talking about other scenarios that you all considered as a possibility that could be scenarios that the filter would be placed in --
A Yes.
Q -- when implanted in a human.
A Yes.
Q And would you answer the questions I asked Dr.

(14:27:52-14:28:29)

Begley the same way with respect to the scenario of the upper portion of the arms adhering to the side walls and therefore pulling away during respiratory, and the loosening of the hooks from the soft tissue causing individual legs to go slack and shed their loads? Would you answer the same way Dr. Begley did, that you all made an assumption about that, but you haven't actually seen imaging, either human or animal or cadaver photographs, that support that that's a phenomenon that occurs?
A Well, broadly speaking, I agree with what Professor Begley said, but I would respond in a slightly different way, which is that we know -- at least I know quite a bit about what is likely, what one should expect in this situation. And this comes from the great deal of experience, if I may say so, I have had with, especially, heart valves, which are subject to some of the same phenomenon that I'm about to describe.
For example, it's -- well, let me back up. First of all, there's quite a lot we do know about what happens in an inferior vena cava. There's blood going through it; it's pulsatile flow; it does expand and contract, at least in some circumstances, as a consequence of a person breathing; and, of course, it's composed of tissue and cells that lighten the tissue wall.

(14:29:39-14:30:23)

And I should comment that I have additional publications, not on medical devices, but on cell mechanics, which remodeling of cells and remodeling of tissue as a consequence of the mechanical effects is one of the features in the topic covered by the paper.

So let me go back to answering the question, which is that from my interaction with the heart valve companies, I know very clearly that remodeling goes on as a consequence of the presence of an implantable device leading to endothelization, that you mentioned earlier, so that the tissue and the cells can grow over the device and entrap the device and therefore cause it to move in a manner that's consistent with the motion of the tissue wall; and furthermore, when loads are applied to cells and to tissue, that they tend to remodel in such a way as to relax the loads which are being applied to them so that there are all sorts of possibilities as to what can happen to the filter when it's implanted in the vena cava, including it being trapped by the wall of the vena cava. It can also perforate the wall of the vena cava because of the tendency for tissue to remodel and relax under the loads which are being applied to the tissue.

And I should also comment at this stage that the sort of imaging that one can do in a live patient would not reveal exactly how the legs are being loaded, whether

(14:31:21-14:31:45)

all six of them are being evenly loaded.

Q True; you can see position and so on.

A Yes, but the precision by which you can do the imaging would not reveal the question of whether the legs are evenly loaded or not; and therefore, Bard would not know whether all of the legs were equally loaded when in an implanted device.

And I should comment that I know this from concerns raised by trying to image heart valves to determine exactly their location and position when they're implanted because that does relate to how they're loaded en vivo, and --

Q And it's quite variable?

A And it's quite variable.

Q As it probably is with IVCs as well?

A Yes.

Q And back to my point --

MR. HARTLEY: Did you finish your answer?

THE WITNESS: Yes, I did.

BY MS. DALY:

Q With respect to the arms adhering to the side walls and pulling the arms outwards --

A Yes.

Q -- to what extent did your investigation try to model that?

(14:32:39-14:33:15)

A The way that we did model it is that we undertook finite element analysis using a three-dimensional model of one arm, although it was a truncated section of one arm, and we imposed a displacement on the truncated end of that arm to reflect the fact that the rest of the arm would be trapped in the vena cava wall and would force that segment of the arm to move in a manner consistent with the motion of the vena cava wall.

Q And what Dr. Begley described about that 3-D FEA -- what variables were put in, whatever you included in the modeling -- do you agree that he was complete in his description of that?

A Yes, I agree that he was complete concerning the things that were needed to do that analysis.

Q Okay. What was he not complete about?

A Well, he didn't model the inelastic -- not the inelastic -- the shape memory behavior of the Nitinol, which was irrelevant to the problem that we were addressing.

Q Okay. With respect to this other thing, the loosening of the hooks in the soft tissue causing the legs to go slack, you all did not do an FEA to demonstrate that?

A No.

(14:34:03-14:34:29)

Q That is one of the things that I guess Dr. Begley called a "possibility" that he was calling out as a red flag?

A I think he said it was a "probability." He did call it a "possibility" at some stages, but then adjusted his description to describe it as a "probability" for the reasons that he went through, which is that it's essentially impossible to assure that the legs would all be equally loaded. And the only sensible assumption that Bard should have made is that only three of the legs would be loaded because three of the legs would keep the filter in a stable location.

Q But again, that's an assumption; true? Without testing and without modeling?

A It is an assumption that Bard should have made.

Q But that's not my question to you. With respect to what you just said about "possibility" versus "probability," that phenomenon is an assumption that you and Dr. Begley are making?

A It is an assumption.

Q Okay. And consequently, an assumption -- to make an assumption be probable, don't you agree from an engineering standpoint you would have to have some modeling or some testing?

A No, I disagree. There are many things that one

has to assume, but one makes the assumptions on a logical basis, does so in a manner which is conservative, and within a reasonable envelope of considerations, represents a worst case that can arise.

For example, you do not go inside a patient and measure their physiology; you don't go inside a patient and measure their tissue mechanical characteristics; you don't go inside a patient and measure in detail the way that the blood flows through a vessel within their body before you implant the device; and therefore, you must make assumptions about the conditions which will be met by the device.

Q Correct.

A And that is standard engineering procedure.

Q But it's still an assumption; it's not necessarily hard science?

A Engineering is not science, and science is not engineering.

Q Okay. But it's not necessarily hard engineering?

A It is hard engineering. I agree, it's not hard science, but it is hard engineering.

Q And it's not necessarily hard medicine?

A No, I -- I'm not -- I am not a doctor. I am not claiming to have any knowledge of the ability to practice

medicine, but I do know that medicine is much more like engineering than it is -- it's not a science. Medicine is --

Q Which is something that the medical device manufacturers have to deal with, isn't it, because it's not an exact science; you would agree with that?

A I agree with that, yes.

Q And even person-to-person variations can happen that impact medical devices and their usefulness or their helpfulness or their failure; true?

A Yes, and those person-to-person variations, within a reasonable level of understanding, are norm; and therefore, can be anticipated.

Q Would you agree that despite whatever testing one can do to a medical device, until you implant -- if it's an implantable device -- until you implant it into a human being, you are not going to have complete information about how that device actually does in a human?

A You will not have complete understanding or knowledge of how it would perform in the human being, but you can do sufficient preparatory work to ensure that your -- that the likelihood of being surprised about what happened is very, very, very low. Many of the heart valve companies that I work with have never had a failure

of their heart valves, and that's because they do good engineering before they take the device to clinical trials to test it out.

Q Are you aware of any IVC filter manufacturers never had a failure?

A I do not have that knowledge.

Q The other FEA work that Dr. Begley and I were talking about was the modeling of the wire against the sheath.

A Yes.

Q Do you agree that he gave me all of the variables, criteria, whatever was put into that model?

A Yes.

Q Do you agree with what he said the findings of that were?

A I do, yes.

Q Do you have anything you want to add to that -- testing?

A No, except it wasn't testing.

Q Modeling, sorry. And you have done no additional testing -- physical testing, bench testing, animal testing -- as Dr. Begley has not done, in addition?

A I have done no additional testing.

Q Now, there are some comments in the report, for

example, on page 2 --

And this has previously been marked as Begley's 6. So we'll put a -- make it "6."

A Page 2?

Q Yeah, page 2.

A Okay.

Q There are couple of places in the report where the report talks about deductions about what Bard's considerations were. And here's one at the beginning of your report, portion 2. Quote, "Based on our review of the Bard documentation, we deduce that their principal consideration of in-situ loading pertained to a full blockage of the filter due to arrival of a clot in the blood flow, thereby inducing tensile strength in the legs caused by blood pressure. Bard's analysis assumes all legs are sharing an equal fraction of the load. Such an assumption is not conservative." Where do you believe you got the information that that was Bard's assumption?

A It was based on a reading of the document and the fact that I saw no statements that suggested that other concerns were uppermost in the minds of those that were developing the design and analyzing the behavior of the device on the load.

Q And when you say, "Reviewing the document," do you mean that whole list of documents?

(14:41:16-14:41:54)

A Whole list of documents that are in that letter.
Q And do you know that you don't have all the documents that were produced in this litigation?
A If you're telling me I don't have all the documents, then I accept that statement.
Q And let's talk a minute about other information that you reviewed. Have you read any deposition that's been given in this litigation?
A No.
Q And have you talked to anybody who has ever been with an IVC medical manufacturer or anybody who was formerly with Bard about Bard's process and considerations in the development of the recovery?
A No.
Q Have you talked to Dr. Ritchie about it?
A I have talked to Dr. Ritchie, yes.
Q And to what extent did you all share information?
A We discussed the likely nature -- or not the likely -- but the deductions about the nature of the failures and the fact that they are clearly fatigue failures and they clearly indicate high stresses being present in the device.
Q Would you agree that of the filters that we have to look at, the plaintiffs' explanted filters, that there

(14:42:49-14:43:15)

are a number of fractures in different areas in the filter?
A If you design different areas as immediately adjacent to the sheath -- and I'm using that term precisely, which means within a few microns of the edge of the sheath -- at the first bend where the arms are moving as you move along the arms away from the sheath, there are failures there; and then in the legs, there are failures mainly down the knee of the hook. So in that sense, I agree that there are failures in different areas of the filter.
Q And when we go through the individual plaintiffs, you're going to help me, if you can, tie the fractures that are seen there to your theory of what caused that; okay?
A Yes.
Q Okay. You heard Dr. Begley's and my discussion about the welding issue?
A Yes.
Q Are you critical of the use of welding to put the wires in place in the first place?
A Not of -- no, not of welding the wires in the first place.
Q So how would you describe your criticism of the welding situation?

(14:44:08-14:44:29)

A That it was poorly controlled and that the consequences were -- in terms of what I saw in the documentation, the consequences were not explored in terms of how that might make the device vulnerable to failure.
Q Do you know of any plaintiff filter that you would attribute the weld issue to a fracture in that plaintiff's --
A No.
Q Okay. Let's talk about the fluid drag forces for a moment. No, let me go back.
Was there anything else that you and Dr. Ritchie talked about?
A No.
Q Have you talked to Scott Robertson?
A No.
Q Do you know him?
A No.
Q Have you talked to any of the other experts who have given reports for the plaintiff in this case?
A No.
Q And you've read Dr. Fasching's report?
A Correct.
Q Do you know her?
A No.

(14:45:16-14:45:56)

Q Then let's talk about fluid drag forces. If you look at page 3, the first full paragraph -- and I asked Dr. Begley about this -- the first sentence is, quote, "Fluid drag forces acting on arms and legs during normal unblocked operation were apparently assumed by Bard to be negligible." What is the basis for that?
A That there was -- mainly that there was no effort -- in the documentation that I saw -- to analyze the effect of that fluid drag on the arms or the legs and to identify what level of stress might be associated with the fact that there would be drag caused by the blood flowing past the wires.
Q And then you all did some analysis or some research -- I don't know what you want to call it -- and you came up with a fluid drag force on the wires as small, on the order of one Newton slash "M"?
A One Newton per meter, which means that if you had an arm of a length one meter, there would be one Newton load applied to it. Yes, but I forgot what the question was.
Q The question was, you either researched or did something --
A Yes.
Q -- to come up with that and determine that the drag forces -- sorry, the fluid drag forces on the wires

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were small?
A Yes. We looked up -- I looked up Batchelor's book on fluid dynamics, found the section on drag caused by fluid flowing past a circular cylinder, and used the formulae and the diagrams in that -- in those pages of the book to deduce that with the velocity of the fluid involved in the vena cava and its viscosity -- the viscosity of blood and its other properties that might be relevant -- that this would be the level of drag that would be imposed on the wire in those circumstances.
Q Okay. So you're critical of Bard for not considering the level of drag that you found?
A I am critical of the fact that they did not consider the drag on the wire, come to their own conclusions about what level that drag force would be, and impose those drag forces on the wire in a model or a finite element calculation to estimate what level of stresses they would produce in the wire.
Q And then, did you all do that, model that drag force?
A Yes, that's the -- that leads to the number here, one Newton per meter.
Q So that's what you did to get that?
A That's correct, yes.
Q And the impact of that on fatigue is what?

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(14:48:24-14:49:02)

A Well, the flow in the vena cava is "pulsatile," which means that about once every second, the blood stops and starts, which means that the loading goes through cycles, which is the classic circumstance that can cause fatigue in any system, any engineering mechanical system; and since -- I used to know this number by heart because of all my heart valve work -- but there's millions of cycles per second -- per year involved in the circulatory system and therefore you quickly ramp up very, very, many, many millions of cycles whenever loading is being caused by the blood circulating within the human body. And therefore, even with very low levels of drag force, one should at least be concerned that they can generate stresses that could lead to fatigue failure, given a long enough time of implantation.
Q Are you of the opinion that the Bard testing, the respiratory diaphragmatic testing that Bard did and submitted to the FDA, did not simulate this sort of force?
A I saw nothing in the documentation I read that indicated that those kind of tests, except animal modeling -- that was the only modeling, filters in animals -- but that's the only testing that I observed would involve drag forces coming from blood flow.
Q So you're saying that the respiratory testing

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that they did would not be adequate to simulate that?
A The respiratory testing as -- just make sure I understand what you're describing as respiratory testing -- that is the test where the filter is placed in a tube, and the tube is dilated to expand its diameter and contract its diameter, and that would not simulate the effect of pulsatile flow of the blood going past the filter.
Q How would you do that?
A You would put the filter in the same kind of tube and attach it to a pulsatile flow system, which are very commonly used in heart valve companies because of the fact that the issues are almost identical; you've got pulsatile flow of the blood going through the device opening and closing it, in that case, so such testing devices are quite common. And you would put the tube in the fluid circuit of such a device and carry out tests over many millions of cycles to see what happens. And you would simultaneously dilate and contract the tube.
One would have to design the protocol for the test accordingly, but I think that's quite easily done. And therefore you would simultaneously apply the dilation that's caused by the respiratory action and the pulsatile flow that's associated with the blood moving past the filter.

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Q So that could be done?
A It could be done.
Q Okay. Sitting here today, you don't have -- you have not tested an IVC filter in that way?
A No.
Q Nor have you modeled a test like that to determine whether a test like that would tell us more?
A Well, "modeling" is a very broadly defined word, and I would say we have done modeling because we've calculated drag forces; we've estimated stress levels; and we've looked at diagrams that indicate the number of cycles it would take at those stress levels to fail the device, fail the material in fatigue, and the number of cycles involved. Although we didn't write it down in the report, the number of cycles involved at the stress levels we estimated are very small, of the order of hundreds of thousands.
Q Okay. And having not done the test that you've just talked about, doing the respiration with the flow --
A Yes.
Q -- you are not able to tell me how that would come out?
A No, it's true. Well, actually, can I revise my answer?
Q You can always revise your answer.

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A Yeah. I know that I can set up the test in such a way that I can make it fail in a thousand cycles, so in that sense, I do know. But that would not be --
Q Well, you can set up the test, but that might not necessarily be what's happening in the human.
A I agree it would not reflect the loading en vivo, but what I'm saying is that one can anticipate the outcome of the test in some circumstances.
Q But we haven't done it, so we don't know how it would come out?
A We haven't done it, so we don't know the outcome of the test in other circumstances.
Q Okay. Now, let's talk about the three -- we talked about the three-dimensional finite element test, which is the wire against the sheath?
A The three-dimensional finite element analysis is the arm being displaced on its end.
Q And we've talked about that?
A Yes.
Q And you don't have anything further to add to what Dr. Begley said about that?
A No.
Q And you don't have anything further to add to what Dr. Begley said about the two-dimensional finite element analysis?

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A No.
Q Now, if you look at your report, page 4, the top sentence, "We wish to emphasize that it is impossible to accurately quantify the stresses in the implanted device where the wires emanate from the surrounding sheath." What was the reason for that sentence?
A The reason is that the specification of the shape and the design was not clear enough in the documents that we saw to enable the analysis to be carried out in a way that reflected precisely how the device is shaped and how it would be loaded.
Q So that's based on the information you had?
A Based on information that we had, right.
Q If you had had an exemplar filter, for example?
A Well, we did have an exemplar.
Q But you couldn't cut that one up because it belonged to somebody?
A Yes.
Q If you had had an exemplar that you could do with as you wished, would that have informed you further?
A It would have in the sense that we could then analyze that specific example, but one has to be very careful because that doesn't mean that that is a typical example of the device as produced. Therefore, it is better to work from engineering drawings and to utilize

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the tolerances that were specified in engineering drawings to identify the worst case shapes that can arise and to then analyze the device based on the deductions that come from such information. But one of the problems we faced is that such information was not clearly available from the drawings and the other documentation that we had.
Q Okay. Do you have any reason to believe that these filters as manufactured -- I'm talking about the recovery ones -- had any significant variability over the course of the manufacturing, one to the next?
A I have no information regarding that.
Q Do you have any information that anything about the manufacturing process, as opposed to the design process, contributed to fractures in these filters?
A Certainly looking at the SEM micrographs raised serious concerns in my mind because of the gouges, because of other marks that were visible on the surface of the wires, that in standard practice one would implicate in the possibility of fatigue failure and therefore do something to eliminate or to assure oneself that they, in fact, would not lead to fatigue failure within the time that the device had to operate in whatever it was being used for.
Q Are there any of the plaintiff filters -- that

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we'll look at in a minute -- that you believe fractures occurred from that situation?
A I'm not sure if it's a G2 or recovery, but my recollection is that there's one where the fracture starts from a defect on the surface, at the surface.
Q And do you think it's possible with Nitinol wire to ever be completely free of some sort of surface issue?
A It is never possible to be completely free of defects on the surface of any metal or engineering device, but it's certainly possible to reduce the level of defects that were present on the surface of the devices that I saw in the SEM micrographs.
Q Are you going to testify about electropolishing? It's not in the report.
A I am not going to testify regarding electropolishing, although I can respond to your question by saying that I do know that electropolishing would reduce the level of roughness present on the surface of the material. And I do also know that many medical device companies use electropolishing and are very, very, very careful about the surface finish to their devices for the reasons that we are discussing.
Q Are you going to say that any particular plaintiff's filter fractured due to a lack of electropolishing?

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A No.
Q You heard Dr. Begley talk about the "pre-crack"?
A Yes.
Q Is that what you called it? The sheath issue against the wire? Do you have anything to add to that description or that opinion?
A No.
Q What about to the issue of wire-to-wire contact? Do you have anything additional to say about that?
A No.
Q Do you know of any of the plaintiff's filters where you believe that the fracture was a result of wire-to-wire fracture?
A To my recollection, and I don't know whether it was a G2 or a recovery, but one of the fractures is in a location where there is roughness on the surface that could be associated with fretting between the wires as they come into contact.
Q And I forgot to ask Dr. Begley about that sentence in your report, about the fretting.
A Yes.
Q So would you go through what your analysis was and your conclusion about fretting.
A Well, fretting involves the contact between two surfaces that then move relative to each other and rub

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against each other, and that process can generate the initiation of fatigue cracks and defect fatigue damage in the material which can then eventually fail the device as a consequence of the extension of that fatigue damage. So --
Q And when we go through these, you'll show me if you see an example that you believe is fretting?
A Yes.
Q Is there any other type of testing, other than what was described by you thus far or by Dr. Begley, that you are critical of Bard not doing?
A Yes. Although it really sort of amplifies on what I was saying before. For example, in the kind of test that I described, one would make sure that only three legs were hooked into the tube wall, and just as -- and I can amplify on something else that Professor Begley said, which is that testing should have been done in tubes of various diameter within the range of the diameters of the vena cava that the implant -- the filter is qualified for and lie within the range of counter-indications that were specified by Bard.
In particular, I would have wanted to see a test in the largest diameter of vena cava that was allowed because it is my deduction that that would be the one that would lead to the most severe concentration of

(15:03:35-15:04:18)

stress between the wire and the sheath at the location where the wire can contact the edge of the sheath.
Q Do you agree that in the past decade, let's say, that with respect to implantable medical devices, there has been an evolution in improvement in numbers of those?
A There has been an improvement, but there's improvement all the time, and -- but I would say that the most dramatic period of improvement was about -- between about 25 years ago and 20 years ago. So that by 10 years ago, there was a culture and a requirement -- I should back off the word "requirement" -- but there was certainly a culture and there was the understanding that very serious consideration should be given to the possibilities that an implantable device could experience to assess whether it would fail in fatigue during the lifetime of its implantation.
Q And do you agree that the information we get from the field from clinicians and even patients who have these medical devices implanted help us as engineers and as medical device manufacturers to improve our product?
A Yes.
Q And actually, that's a very valuable bit of information for the improvement of products?
A Yes. But as Professor Begley stated, you shouldn't do the experiment in the human in a manner that

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places the human at risk when you can readily avoid that risk.
Q Well, and that's one problem that manufacturers of medical devices have in any event is the issue of clinical testing; right?
A Yes.
Q And there are ethical considerations or restrictions for clinical testing; true?
A Yes.
Q And depending upon the device, there are sometimes limitations on clinical testing because you can't get people to do it?
A Yes.
Q Okay. And at some point, the device has to be implanted in people to see how it does?
A I don't think that's true. If you come to the assessment that the device is too great a risk --
Q Of course.
A -- to implant, then one should not proceed.
Q Of course. But in the end -- you can do whatever testing you do -- we still tend to be informed further, beyond whatever type of testing could have been done, once it's put into the person; true?
A At least in -- yes, I agree.
Q Okay. Let's look --

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A Can I just respond?
Q Yes.
A One would hope that the experience that one has is a null data set; in other words, that it doesn't fail.
Q That's the goal?
A Yes.
Q All right. Can we look through Dr. Fasching's report, and if you would rather look through Dr. Ritchie's report for this, we can do that.
A Can I look through Dr. Ritchie's report?
Q Sure. Why don't we take a minute.
A Okay, fine.
MS. DALY: Let's take a break.
VIDEOGRAPHER: We're going off the record, and the time is 3:06 p.m.
(Break taken.)
(Mr. Begley left.)
VIDEOGRAPHER: We are back on the record, and the time is 3:15 p.m.
BY MS. DALY:
Q Dr. McMeeking, when we took the break, the question on the table is if you would go through either Dr. Ritchie on Dr. Fasching's -- whichever you prefer to use -- SEM pictures, and I believe you're going through Dr. Fasching's?

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A Yes, that's correct.
Q And if you would do two things at once for me. If you would call out anything that she labels those pictures that you do not believe the SEM shows or that the SEM shows differently; and then if you will also plaintiff-by-plaintiff call out any SEM that you think represents some fracture that you think could be associated with any of the issues you've raised.
A Well, I mean, they're all caused by the issues that we've raised in the sense that they're all fatigue failures and they're all caused by levels of stress that would cause fatigue. And, you know, we've identified high stress as an issue that is associated with the design of the filter. For example, it looks to me that the Carnehl arm -- I'm not sure if that's a G2 or a --
Q It's a G2.
A A G2. But the Carnehl arm could well be fretting because of the surface marks adjacent to the source of the fatigue.
What I can say is that, in each of these cases, I agree with her that the source of the fatigue -- the beginning of the fatigue failure is where she says it is, and that then that -- for example, in the case of the Carnehl one, it's possible that fretting was associated with the way that that fatigue got started.

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Q All right. You can keep going.
A Can you remind me what issues we were talking about?
Q We're talking about -- here are the ones that I believe you talked about. We're talking about the chamfer issue; the wire against the sheath; wire against wire where it might -- where in your view it could be caused by the arm stuck in the vessel, expanding; where it could be the legs not loading all in a balanced way.
A Okay, so, Bloomquist -- again, I don't -- it says, "Recovery," so it should be recovery --
Q Right.
A I would say that both of the arm failures are associated with the fact that there's -- that it's close enough to the end of the sheath for that to cause problems in terms of the level of stress which is generated. In the case of the Carnehl, which is a G2 -- should we just skip over that or is that --
Q We might as well go through them.
A Okay. So in the case of the G2, I would say that Arm 1, as she depicts it, is close enough to the sheath for the raising of the stress by the sheath to be an issue in how that fatigue got started.
Q And let me say this one thing while we're on this G2. There will be a whole different deposition

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where we talk about G2 --
A Yes, I understand.
Q -- and it's different. But to the extent that it's anything that you've already talked about that's the same in this model, go ahead and call that out.
A Okay. I would say that Arm 2 is in the bend location where stresses can be high as a consequence of how the arms get loaded.
Q In the Carnehl?
A In the Carnehl. The Ciaburri is a failure -- in the Arm 1, as she calls it, is a failure that to me is associated with the raising of the stress by the adjacency of the location with the end of the sheath.
Q So sheath wire?
A Sheath wire.
Q Okay.
A From her report, I can't say anything about the Clark case.
Q Okay.
A There's no pictures of where the actual failure is.
Q Do you remember anything about the Clark case independently?
A No.
Q Okay, that's fine.

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A I'd have to refer to Professor Ritchie's report to say anything further.

In the case of the Gray, Arm 1 is adjacent to -- the failure is adjacent to the end of the sheath, and I would implicate the effect of the end of the sheath on the way that stresses have been raised and in the shape of failure.

In the case of Arm 2, that's in the bend location where we find the stresses to be high in certain circumstances.

VIDEOGRAPHER: Sorry to interrupt, but I want to point something out. That vehicle parked right over there is reflecting onto our witness, and look at the screen.

MS. DALY: Yeah, let's stop because all of a sudden you're completely -- it looks like you're on a beach. We need to move him.

VIDEOGRAPHER: Right. Going off the record. The time is 3:21 p.m.

(Discussion held off the record.)

VIDEOGRAPHER: We are back on the record, and the time is 3:24 p.m.

THE WITNESS: Shall I keep going?

MS. DALY: Yes, thank you.

THE WITNESS: I won't say anything about the

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legs because we didn't do anything in the way of stress analysis except to point out that the stresses are probably -- or not probably -- we would assess them to be twice as high as Bard thought them to be, but I don't -- I can't comment in detail on the leg fractures in any case.

BY MS. DALY:

Q And your assumption of what Bard thought them to be is based on just the material you have?

A Just the material I have, that's right.

The Lindsey recovery, both the arm failures are adjacent to the end of the sheath, and in my assessment are clearly associated with the stress raising that that adjacency caused in the arms.

The Lynch case, the Lynch recovery filter, Arm 1 is a fracture adjacent to the end of the sheath, and in my assessment, the raising of the stress by the end of the sheath where the arm would come into contact with it is implicated in the fatigue and fracture of that arm.

Arm 2 is perhaps marginal in terms of whether it's close enough to the end of the sheath and whether it's in the region where the wire bends. Looking at it, as I do now, it looks to me like it's in the region where the arm bends and therefore is in one of the locations where we find stresses to become high in the arms in

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certain circumstances.

The Newton case, both of those failures are close enough -- at least in the view that is in Figure 30 of Dr. Fasching's report -- are close enough to the end of the sheath that I would implicate the end of the sheath in the raising of stresses that would initiate the fatigue failure in those cases, but I guess I would prefer to see another picture just to be sure because the perspective in this case is not very good for making that assessment.

And in the case of the Newton Arm Number 2, it looks to me like there's a defect on the surface which may be a surface mark or something like that from the manufacturing that is associated with the initiation site. So that is one point of relevancy.

And in the case of the Stahl, Arm Number 1 -- there are a lot of broken arms in this case -- Arm Number 1 has broken where the first bend takes place after the wire has come out of the sheath, and that's one of the locations where we find the stresses to become high in certain circumstances in which the arms can be loaded.

Arm 2 and 3 look to me as if they're in that same location and are subject to the same concern of the stresses being high there in certain circumstances.

I think that's the end, isn't it?

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Q Yeah, I think that's right. I'm not keeping track.

A I'm looking at exemplars now.

Q Thank you very much, that's great. Few more questions. Now, as you described your role as an expert in this litigation, you said that you were to look at the devices to see if there was concern of susceptibility to failure?

A Yes.

Q I think I quoted you right, okay. And you did that as best you could with the material that you had?

A Correct.

Q Which I will represent to you is not all of the Bard produced materials nor all of the testing that Bard did.

A If you say so, I accept that.

Q Okay. And which also did not include your review of the failure investigation report of August 2004 that Bard did, once it was reported to them that fractures were occurring; correct?

A Can you clarify? Was that included in the list of documents?

Q It was not.

A Because I have seen some material that indicates that further work was done, given that there had been

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failures observed. But I'm not sure if it -- obviously it wasn't the document you're talking about.
Q Right. You have seen, for example, there's a summary by a man named Avijit Mukherjee --
A Yes.
Q -- that talks about the investigation? But you do not have amongst your documents the 199-page investigation report?
A I don't have anything that's 199 pages.
Q Okay. And also your investigation did not include your reading of depositions of Bard personnel?
A That's correct.
Q So you were -- your investigation, your conclusions, are based on what you had to review; correct?
A That's correct.
Q And your FEAs, similarly, were done with whatever information you had available to you?
A That's correct.
Q And FEAs, you would agree, are only as good as what you put into them, variable-wise?
A That's correct, but we do a very good job of that, so --
Q Correct.
A If you don't mind me saying so.

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Q If you had wrong information, you could have wrong outcome?
A Yeah, there's a common expression, "Garbage in, garbage out."
Q Right. And that certain assumptions that you made --
A Can I amplify that response?
Q Yes, of course.
A Which is that, I did look at the finite element analysis. Some of it was done either by or for Bard, and quite frankly, I was appalled at how poorly it was carried out. And it looked to me a case of what I just described, "Garbage in, garbage out."
Q And so you didn't use that data --
A No.
Q -- in yours? Okay. And you also testified that some things that are --
A So can I back up and amplify on that response?
Q Yes.
A We did not -- I did not -- we did not use the results of the inputs or the configurations from those finite element analysis; however, what we did do repeated one of their analyses in the sense that we moved an arm by one millimeter and got radically different results from what they obtained in their analysis, in which their

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stresses were relatively low and not something that would cause you concern. But the concern is that they did the analysis very poorly and they should have done it in a much better fashion.
Q Well, you noticed that -- I think that the -- that that FEA was not done in-house; right?
A Yes.
Q And do you know that they don't have capability to do that in-house, or didn't at the time?
A You're telling me. I don't know.
Q But --
A Can I just comment?
Q Let me ask this question; then you can. What you're saying is that the information that they got, on an outside FEA, you didn't think was -- you did not think was the right outcome?
A That's right, yes. The results they got were meaningless because the analysis that was done was meaningless, but the responsibility lay on the shoulders of Bard to direct their consultants to do a job that was appropriate for the way that the filter was loaded and used.
Q And you don't know how they relied upon or didn't rely upon that particular FEA to which you're referring?

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A No, I don't, but it was provided as one of the few documents that Bard produced in their activities that described finite element analysis of the filter.
Q But it was done after the recovery filter was taken off the market in 2003, don't you agree?
A I don't recall the dates, but I did notice it was sometime into the period that we're talking about. It wasn't right at the beginning.
Q So if they relied on that or didn't, you don't know?
A I don't know.
Q Okay. The other thing that you talked about and put into your report, in addition to doing these specific FEAs, you also made certain assumptions?
A Yes.
Q And again, it's the same thing, "Garbage in, garbage out." An assumption is only as good as what variables you're using for the assumption?
A That's correct. But as I said, the assumptions that we made were quite appropriate, quite sensible, and were the assumptions that Bard should have made in their assessment of the performance of the filter, and they should have done that before they started implanting it in human beings.
If they didn't have finite element capability 10

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years ago -- is that the date we're talking about? Could you clarify? If they didn't have finite element capability 10 years ago, they should have because by then it was a very mature technology; it was commonly available to engineers and companies; and it was not an expensive system to bring in-house and train people to use. By then, it was quite easy to use it in a reliable way, as long as the supervision of what was done was knowledgeable, by which I mean, that the engineers in charge should know what it is they're trying to do, and do it, and direct the analyst to do it properly.

Q And I'm not saying that they didn't do it or they didn't have it. I'm just saying, my question was, the FEA materials you did look at -- I'll tell you they were after the date the recovery was taken off the market -- so you don't know to what extent they relied on that for what purpose?

A No, I don't.

Q Okay. And you don't know, because you haven't seen it, what other analyses they may have done before they put the recovery on the market; fair enough?

A Well, I accept what you're telling me, but what I can say is that we asked the plaintiff's lawyers to seek all finite element analysis that was carried out on the filters. And that's -- the few documents we received

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is all that we got.

Q And testing, you asked for testing too, didn't you?

A Yeah.

Q Okay. Is it your intention to do any physical testing of this filter?

A No.

MS. DALY: That's all I have, thank you.

FURTHER EXAMINATION
BY MR. HARTLEY:

Q Doctor, you made notes during Dr. Begley's deposition. Is there anything on your notes that you didn't get an opportunity to discuss with Ms. Daly?

A We -- I took care of everything that I noted, except one comment which is that when we made assessments of how we should load the arm in our finite element analysis and our consideration of the loading of the device, we took information from Bard's documentation and we looked at those papers that you mentioned, that we were referred to in our list of materials relied upon, and I made the assessment that what we did, what we were going to do, what was in those papers, and what Bard was saying was happening in the vena cava were all consistent. And so we carried out finite element

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analyses that were, in that sense, consistent with the common view as to what was going on in the vena cava. Although, I'm not saying that Bard did everything they should have done. I'm just saying it was consistent with what we saw in Bard documentation and in the papers.

MS. DALY: And with respect to that one thing -- sorry to break in on you.

FURTHER EXAMINATION
BY MS. DALY:

Q With respect to that one thing -- after this deposition when you get a chance to go back to your office, are you able to look at those materials and tell me which document or documents it is that you were describing, for that particular issue, that you used?

A I can.

Q And just let Dean know. That would be very helpful.

A Yes, I can and will. Yes.

MS. DALY: Thank you.

FURTHER EXAMINATION
BY MR. HARTLEY:

Q You indicated during your testimony that you

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were surprised, I guess, at what your analysis demonstrated in light of the stresses that were put on that filter. Had you been implored by Bard before they brought the filter to market, what would you have advised them, Professor?

A I would have advised them to consider two possible routes: One would be to redesign the filter, by, for example, specifying and ensuring that a radius at the edge of the sheath was chosen that would be benign in terms of the stresses that would be generated in the arms that were subject to loading within the device.

And I suppose if the decision was made not to redesign the device, which I would say would be the wrong decision -- and let me back up. There would be other design changes that would be possible, such as changing the diameter of the wires, possibly putting a spacer inside the sheath to keep the wires away from the sheath where they come out of the sheath; one could redesign the shape of the arms to try and reduce the level of stresses that would arise in the circumstances that we were concerned about; and there's other design changes that one could think of making.

But if, let's say, there was a decision made not to change the design for some reason, which, as I said, I would say is the wrong decision, then a more extensive

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effort of testing would be appropriate in the preclinical setting. I'm not saying our models, but in the preclinical setting in the lab to find out whether the device was going to be subject to premature fatigue failures as a consequence of certain things that we're concerned about.

And I would have advised them to carry out much more complete finite element analysis of the device in its three-dimensional shape to get a clear understanding of what the levels of stress are in the device when it experiences certain circumstances such as the ones that we described: The arms being trapped in the vena cava wall; only three legs being properly embedded in the vena cava wall to support the filter in place.

Q Given what you found in your analysis, had Bard done a more robust analysis of their recovery filter, even the elementary level that you all did in this litigation, should Bard have been surprised that the recovery filter was failing?

A If they had done even the more elementary things that we did without even going to finite element analysis, if they had simply did what we call "bean theory" modeling of the loading of the arms and then used standard books to look up stress concentration factors that could arise at the critical locations in the design

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of the filter, if they had even done that, they would have expected to see premature fatigue failures when the device was implanted.

Q You've mentioned "fatigue failures," and that's what Dr. Ritchie has described them as. Does your analysis of the stressors that are on the filter support Dr. Ritchie's opinion that it is fatigue that is causing the fracturing of the filter?

A Yes. Our modeling and stress analysis supports not only the fact that it is fatigue that is causing these failures, but it supports -- well, in a sense, this is topological -- but it supports the fact that the failures occur in the locations that they do.

Q If we look at the exemplar filter you had an opportunity to review, the SEM, as well as Dr. Ritchie's SEMs, your analysis of the stressors that were on the filter, as well as the design, and even Dr. Fasching's scanning electron microscopy photographs, can you say for the filters that we don't have scanning electron microscopy photographs of, that it was the design of the filter, with the stressors that you've been discussing here today, that more probably than not caused the four filters of Mohammed, Evert, Kolenda, and Heidi Smith to fail?

A Yes, I agree it's more probable than not that

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the failures are caused by fatigue from the same sources that we've been talking about today.

Q Do you agree with Dr. Begley that the Bard recovery filter was defectively designed?

A Yes, I do.

Q Do you have an opinion as to whether it was defectively manufactured?

A I think that's more difficult to say in that it's not obvious that the surface texturing was a very big problem in the way that the devices failed; however, I would say that the surface quality was very poor and an engineer would have -- with any sort of experience in the effect of surface texture on the reliability and fatigue life of a device -- they would take steps to improve the quality of the surface.

Q Let me ask you this question then. Can you say that it's more probable than not that the surface finish contributed to the problems that we see with the recovery filter in the fractures?

A Yes, it's more probable than not.

Q All right. One final question. You've been asked about numerous other analyses that Bard's done that you may or may not have seen, that may or may not be in existence. Regardless of any analysis that Bard has done of the filter, in addition to whatever you've seen, did

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(15:45:58-15:46:22)

any of the analysis that they did impact the design of the filter and its ability to fracture and migrate?

A I'm not sure if I understand the question, but can I state it this way, that our observations of the shape of the filter and the drawings that we saw were such that it seemed that no serious analysis had been done on the device that would tell them that this was a bad design.

Q Would it be fair to say that if Bard did additional analyses that you haven't seen, that those analyses missed a spot as well as their previous analyses?

A Yes, because there's nothing that I've seen that suggests that improvements were made to the design to such an extent that it eliminated all the problems we've been talking about.

MR. HARTLEY: Thank you, Doctor.

MS. DALY: Dr. McMeeking, a few more.

FURTHER EXAMINATION

BY MS. DALY:

Q With respect to the surface condition issue, your sort of general comment in the answer to Mr. Hartley's question was that you saw examples of poor surface condition? I'm not rephrasing you perfectly

(15:46:58-15:47:31)

well.
A Yes.
Q Okay. However, when you were going through these particular filters in the Dr. Fasching's report, I believe there was one that you said might -- one arm, Newton filter, that might be related to a surface problem; correct?
A Yes.
Q So the surface problem creating a fracture is really on a case-by-case basis; true?
A Yes.
Q So you were then asked a question of whether you could say in a very general sense, more probable than not, that the fractures in plaintiffs' filters where we don't have the filters to look at them were caused by any of the things that you testified about today; correct? You were asked about that?
A It is more probable than not that those failures were caused by fatigue caused by high stresses from this -- and/or possibly surface finish, but caused by high stresses of the type that we've been talking about from the sources that we've identified.
Q But without looking at them, you cannot be certain?
A One cannot be 100 percent certain.

(15:48:18-15:48:46)

Q And really, the best way to determine that would be to do the SEM and actually look at it, if we have them?
A Well, no, there's an intermediate step, which is that you can image what's left and the other bits that -- if it can be found in the body, and identify the location of those failures. And if they are in the same place as the failures we've been talking about, then that increases the probability that it's from exactly the same source that we're talking about. But I agree it would not take the certainty to 100 percent.
Q Right. And it would be more difficult to make that analysis if the filter is still in the body?
A Which analysis?
Q The analysis of what caused the fracture.
A Yes.
Q And the other thing you were talking about was recommend -- what you would have recommended Bard to do when you talked about additional testing, and you talked about redesign issues; correct?
A Yes.
Q Okay. In those events --
A Excuse me, and I said, "A more complete and accurate finite element analysis."
Q You're right. In the event of redesign, would

(15:49:20-15:49:55)

you agree with me that that would require a full-blown retesting to see if any redesign created a problem in a different area that you hadn't anticipated?
A Absolutely, yes.
MS. DALY: Okay.
MR. HARTLEY: I have nothing further. Thank you, Doctor.
MS. DALY: Thank you very much for spending the whole day with me.
VIDEOGRAPHER: This concludes today's deposition of Robert Maxwell McMeeking, Ph.D. The number of videotapes and DVDs used was one. The time is 3:49 p.m., and we are off the record.
MR. HARTLEY: Do you want to read and sign, Doctor?
THE WITNESS: What does that mean?
MR. HARTLEY: It means that she will type up everything we said today. She will then send you a copy of that, or me a copy. You then have the opportunity to review what you said to make sure it is accurate.
MS. DALY: And mostly it's just some technical term that maybe she doesn't get or --
MR. HARTLEY: Or you can waive the right to read and sign and assume she's going to get it correct.
THE WITNESS: I think it's best to read and

sign.
THE REPORTER: Do I have his address?
(Discussion held off the record.)
MR. HARTLEY: You have 30 days to complete your task. And if you don't complete your task, it's as if you didn't read it.
(Deposition concluded at 3:51 p.m.)

STATE OF CALIFORNIA)
COUNTY OF SANTA BARBARA) ss.

I, ROBERT MAXWELL MCMEEKING, PH.D., hereby certify under penalty of perjury under the laws of the State of California that the foregoing is true and correct.
Executed this _____ day of _____, 2011, at _____, California.

_____
ROBERT MAXWELL MCMEEKING, PH.D.

STATE OF CALIFORNIA)
COUNTY OF SANTA BARBARA) ss.

I, ELIZABETH A. MOOY, CSR NO. 11281, A Certified Shorthand Reporter in and for the County of Santa Barbara, the State of California, do hereby certify:

That, prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify the truth, the whole truth, and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named, and thereafter reduced to typewriting by computer-aided transcription under my direction.

I further certify that I am not interested in the event of the action.

WITNESS my hand this _____ day of _____, 2011.

_____
Certified Shorthand Reporter in and for the County of Santa Barbara, State of California